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Electrical Restoration of the Micturition Reflex

BY

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of the University of Cape Town for the degree of Master of
Science in Electrical Engineering.

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SUMMARY

Numerous attempts at electrical stimulation of the detrusor muscle of the urinary bladder to evoke contraction and evacuation have been carried out over the past decade. A review of prostheses for the restoration of urinary continence and for effecting bladder evacuation, is given. Problems encountered during detrusor stimulation to effect voiding such as pain and increased urethral resistance are due to current spread to the surrounding pelvic structures. To restrict this current spread, sequentially activated multiple bipolar electrodes are employed.

The development of a three-channel vesical stimulator to realize sequential pulsing is described. The inductively coupled device is externally controlled and totally implantable. The system used is believed by the author to be a unique method for transmitting three simultaneous and independent signals successfully to the simple type of receiver used. The good correlation between theoretical and practical results enables the theory developed to be used to predict the performance of coupled coils.

The successful clinical trial of the stimulator in an animal and the good current restricting properties of the device indicate that the system used is a feasible method for the treatment of urinary retention following paraplegia.

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Fig. 1 THE RF SEQUENTIAL BLADDER STIMULATOR

1 INTRODUCTION

Although mortality has declined since the introduction of antibiotics and improved catheter management, urinary tract infection is still a common cause of death in the paraplegic. The aim of treatment of neurogenic bladder dysfunction using electrical stimulation is to restore volitional control of bladder function.

Electrical stimulation of the bladder musculature is aimed at increasing the intravesical pressure with subsequent relaxation of the urethra-vesical junction. Surgical effort is almost entirely devoted to only decreasing outflow resistance.

Increasing bladder outlet resistance by electrical stimulation of the pelvic floor musculature is possible thus preserving urinary continence and eliminating the need for catheters and portable urinals.

The effects of bladder dysfunction include disability due to infection, the disruption of normal life at home and work, and social embarrassment. It is hoped that the construction of reliable stimulator mechanisms will eliminate these problems.

1.1 HISTORICAL NOTES ON THE USE OF ELECTRICITY FOR URINARY BLADDER STIMULATION.

Electrical stimulation of the muscles of the urinary bladder as a means of treating urinary retention was first used by Mc Guire in 1954. Mc Guire also constructed the first wholly implantable device powered by large external coils weighing between 35 and 45 pounds. The work of Mc Guire remained unpublished until 1964 when Boyce et al¹⁰ referred to it in a paper describing the use of a RF stimulator with a portable transmitter.

The first paper to be published on the use of an RF stimulator for the treatment of retention was by Bradley et al¹⁵ in 1962. Further publications followed, amongst them papers by Bradley et al¹⁴ (1963), Ellis et al³³ (1965), Boyarsky¹¹ (ed., 1967) and Scott et al⁶⁶ (1965). Hald and Mygind⁴⁶ (1966) and Hald et al⁴⁴ (1966) suggested electrically induced

fatigue in periurethral muscle as a means of decreasing urethral resistance during electrical stimulation. Also in 1966, Bradley and Conway¹³ suggested an improvement in electrode design to restrict current spread, and in 1969 Timm and Bradley⁸¹ suggested the use of sequential pulses in order to further decrease current spread.

Peripheral nerve stimulation to effect voiding was first attempted by Dees²⁹ in 1940 (Published in 1967). He used a rectal electrode to stimulate the hypogastric plexus and obtained increased intravesical pressure rise without voiding. In 1958 Burghelle et al¹⁶, stimulating the pelvic nerves in dogs were able to induce micturition. In 1967 Habib⁴² evoked voiding by stimulation of the fourth sacral nerve (S-4), and in 1967 Holmquist et al⁵⁰ used dual electrodes to stimulate the pelvic nerves. After a series of experiments in which he stimulated sacral, pelvic and hypogastric nerves to effect voiding, Hald⁴³ (1969) concluded that this method is unsuitable. Friedman et al³⁷ (1972) and Grimes et al³⁹ (1973) used depth stimulation of the spinal cord to induce micturition with more promising results.

In 1972 Chien et al²³ (1973) applied a magnetic field to ferromagnetic plates sutured onto the detrusor and so compressing the bladder. A mechanical encapsulating device was also used by Jagannathan et al⁵¹ (1969). Both methods, whilst producing voiding, caused serious complications.

Treatment of urinary incontinence by electrical stimulation of the levator ani muscle near the bladder neck was first used by Caldwell et al²¹ (1965). The electrical vaginal pessary which stimulates the anterior fibres of the levator ani muscle and part of the intrinsic urethral mechanism in order to effect continence was first used by Alexander and Rowan² (1968). (See Chapters 2 and 3).

1.2

PHYSIOLOGY OF THE URINARY BLADDER AND ITS ELECTRICAL CONDUCTION SYSTEM.

i) Anatomy

The bladder is a reservoir, collecting and storing urine from the kidneys until such time as it can be expelled.

In man the bladder is situated subperitoneally most probably due to the erect posture. It is supported by the pelvic and urogenital diaphragms and is also connected by musculo-fibrous bands to the pubic bone, rectum and vagina. (Hald⁴³, 1969).

The detrusor or bladder musculature is smooth and consists of three layers: inner longitudinal, middle circular and outer longitudinal. This is a simplified view since muscle fibres run through all three layers and in all directions (Woodburne⁸⁶, 1967).

The posterior part of the bladder neck is formed by the trigone and contains the ureteric openings. The existence of an internal sphincter has no anatomical basis (Woodburne⁸⁶, 1967; Hald⁴³, 1969). Guyton⁴¹ (1971) labels the trigonal muscle as the internal sphincter of the bladder.

Just beyond the bladder, the urethra passes through the urogenital diaphragm, the muscle of which constitutes the external sphincter of the bladder (See Fig. 2).

ii) Bladder nerves

Innervation of the urinary bladder is too complex for more than a simple summary to appear here. Useful references are Boyarsky¹¹ (ed., 1967), Hald⁴³ (1969), Guyton⁴¹ (1971), Pederson⁶⁴ (1971) and Bors and Comarr⁹ (1971).

Contraction of the detrusor is a reflex action excited from the bladder itself. Motor nerve supply to the detrusor is parasympathetic and is mediated over the sacral cord segments 2, 3 and 4. Detrusor inhibition by sympathetic innervation is unlikely in man.

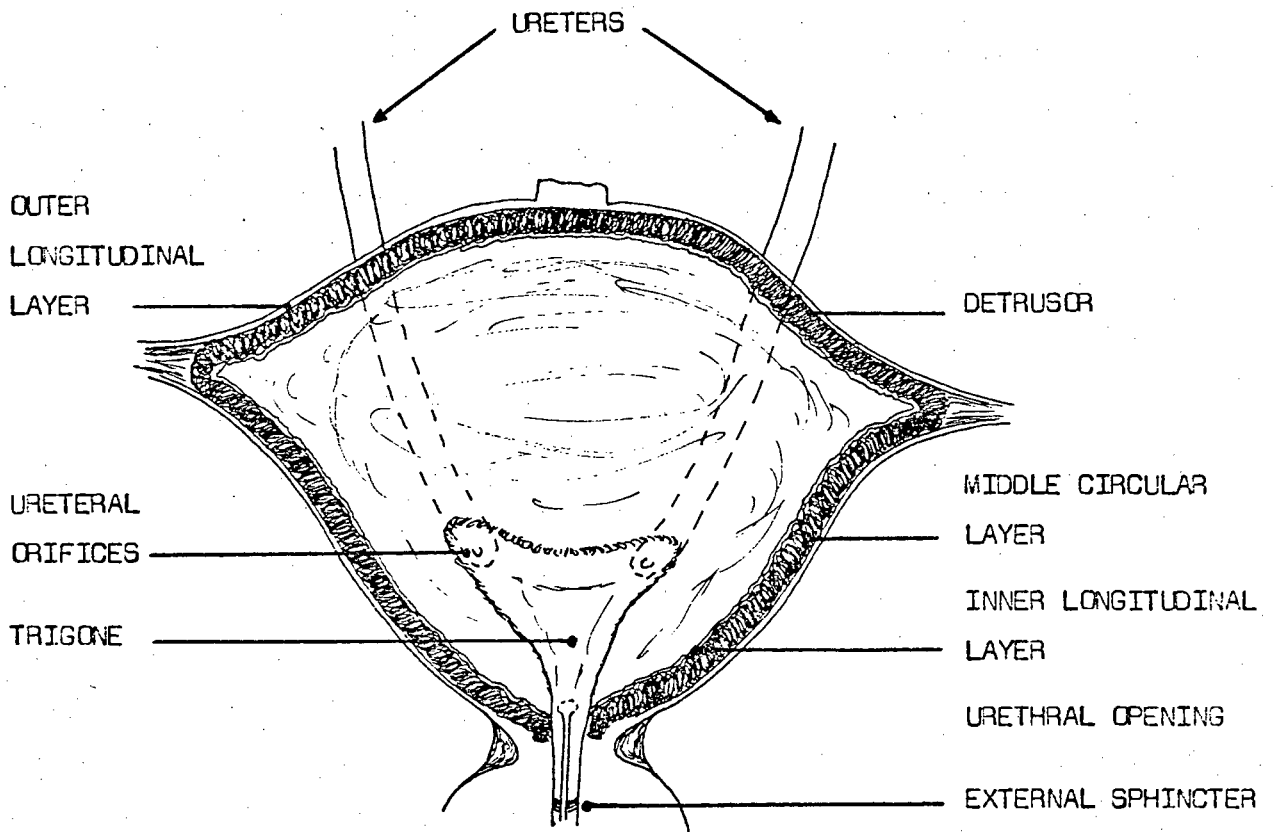


Figure 2 ANTERIOR SECTION OF MALE URINARY BLADDER

All bladder nerves contain both afferent and efferent fibres. The afferent fibres have their origin in the bladder and carry pulses from the stretch receptors in the detrusor. The efferent parasympathetic fibres are the main motor nerve of the bladder and are capable of contracting the detrusor.

Trigone motor innervation is from the sympathetic nervous system originating from the upper lumbar and lower thoracic parts of the spinal cord (T11-12, L1-3).

The external urethral sphincter which is usually reflexly contracted, is supplied by the pudendal nerve. The smooth muscle of the urethra receives nerve fibres from the pelvic nerves.

iii) The Physiology of Micturition.

Micturition is the process whereby the bladder empties itself when full.

The sequence in normal micturition is as follows:

(a) The bladder fills until tension in its walls rises above a threshold value eliciting a nervous reflex called the "micturition reflex".

(b) The reflex action greatly increases intravesical pressure which acts in a downward direction pushing the bladder neck open so that it forms a funnel. A conscious desire to urinate is felt.

(c) On the release of cerebral inhibition, relaxation of the external sphincter and pelvic floor occurs.

(d) After emptying, the external sphincter and pelvic floor contract whilst the detrusor relaxes thus ensuring continence.

The role of the trigone during micturition is to block off the ureterical orifices so that urine does not reflux into the ureters. In contracting, the trigone may aid the opening of the bladder neck (Hald⁴³, 1969).

The concept of an internal vesical sphincter which relaxes when the detrusor contracts is not valid, and continence is maintained by virtue of the resistance presented to urine flow by the flask-like shape of the bladder neck (Greene and Emmett³⁸, 1963).

Relaxation of the urethrovesical junction is sequential to contraction of the detrusor (Conway and Bradley²⁷, 1969).

Significant alteration of micturition and incontinence have not been observed as a result of paralysis of the external sphincter. The purpose of the external sphincter is to enable interruption of urination and to voluntarily delay voiding (Greene and Emmett³⁸, 1963).

iv) Neuro-muscular Transmission in the Bladder

Smooth muscle fibres are about 1-10 μ in diameter and 0.5 mm long. Nerves to smooth muscle are about 0.5-1.5 μ in diameter and have no myelin insulation. Changing the membrane resting potential sufficiently will increase the sodium ion permeability. As the positive sodium ions enter the axon, the membrane potential is still further decreased thus producing a regenerative action. At the point of depolarization, circulating currents affect the axon ahead, causing it in turn to be depolarized. Thus an action potential is propagated along the nerve fibre (Lale⁵³, 1966). There are more muscle cells than nerve endings in the smooth muscle of the bladder so that each motoneurone divides within the muscle, branching to many muscle fibres (Fletcher and Bradley³⁵, 1969; Lale⁵³, 1966). Hillarp, however, found that several nerve fibre endings converged on each muscle cell (Hald⁴³, 1969).

Denervated detrusor muscle is electrically inexcitable so that contraction is evoked by excitation of the neural conduction system (Timm and Bradley⁸⁰, 1968). Thus the application of an external stimulus should not be directed at direct excitation of the muscle fibres.

Fredericks et al³⁶ (1969) observed a series of rapid biphasic spike potentials in the detrusor as the detrusor contracted and the intravesical pressure rose. Contraction and relaxation in smooth muscle is relatively slow, the excitation of one fibre spreading to neighbouring fibres. Thus the spike potentials observed by Fredericks et al elicit repeated contractions adding to each other to produce a sustained contraction known as 'tonus' (Lale⁵³, 1966).

The main neural pathways to the detrusor are located at the lateral ligaments of the bladder. In the rostral portion, these neural pathways are located about two thirds of the distance from the outside to the inside of the bladder wall (Timm and Bradley⁸⁰, 1968). Excitation appears to be initiated in the dorsal urethrovesical junction proceeding superiorly to the fundus and then ventrally, laterally and inferiorly to the urethrovesical junction (Conway and Bradley²⁷, 1969).

1.3

URINARY INCONTINENCE AND RETENTION

The intention in this section is not to list in detail the causes of urinary retention and incontinence but rather to briefly indicate the types of neurogenic bladders resulting from such causes.

Neurogenic vesical dysfunction is defined as urinary bladder dysfunction resulting from lesions of the central and peripheral nervous systems (Hald⁴³, 1969; Emmett and Greene³⁴, 1963). The type of bladder that will result following injury to the spinal cord depends on the location of the lesion. Lesions in the cervical or thoracic levels of the spinal cord (viz. above the reflex centre for micturition) are classified as upper motor neuron lesions whilst lesions through the conus medullaris or sacral nerves in the cauda equina (viz. below the reflex centre for micturition) are classified as lower motor neuron lesions (Comarr²⁶, 1965).

Most works on neurological urology list specific types of neurogenic bladders. The classification of D.R. Smith⁶⁸ (1966) has been used here.

The reflex or automatic neurogenic bladder is the result of a partial or complete transection of the cord above the sacral level and may be caused by trauma, tumor and multiple sclerosis. As the bladder fills, strong uninhibited contractions occur and involuntary urination follows. The capacity of the bladder is small and residual urine is present. True sensation of fullness is lacking.

Incomplete lesions of the cortex or the motor tracts result in the uninhibited neurogenic bladder. Causes are brain tumours, multiple sclerosis and possibly cerebrovascular accidents. Strong, uninhibited contractions cause involuntary voiding before the bladder reaches full capacity. There is no residual urine and sensation is normal.

Lower motor neuron lesions result in a flaccid or atonic bladder. Causes are trauma, tumours, tabes dorsalis and various congenital anomalies. Because the bladder is flaccid and there are no involuntary detrusor contractions, voiding is impossible. The bladder has a large capacity and overflow incontinence is usual. There is no sensation of fullness.

Residual urine resulting from the inability of the bladder to expel all its contents, and the refluxing of urine due to abnormally high intravesical pressure during uninhibited contractions are the main problems associated with neurogenic vesical dysfunction. Electrical stimulation to effect voiding can eliminate catheter drainage in the case of residual urine thus preventing chronic infection, deterioration of the upper urinary tract and numerous other problems (Emmett and Greene³⁴, 1963).

2

A REVIEW OF PROSTHESES IN URINARY INCONTINENCE

2.1

INCONTINENCE DEVICES

Incontinence may be the result of impairment of the pelvic floor musculature and urethra with subsequent reduction in outlet resistance, or due to either a reflex or uninhibited neurogenic bladder where strong uninhibited contractions occur causing involuntary voiding, or an atonic overdistended bladder with resultant overflow incontinence.

Prostheses to restore continence are used where surgery has either failed or is considered unsuitable, and act either by electrically stimulating the external sphincter or by occluding the urethra or both, thereby increasing outflow resistance.

i) Berry Prosthesis

The Berry prosthesis, made of acrylic, is used to control incontinence by kinking and compressing the bulbous urethra just below the urogenital diaphragm. Its inventor claimed success in 5 out of 11 cases (1961)⁷. A.M. Raney⁶⁵ (1969), however, found that in 8 cases, one patient remained continent for 2 months, 3 patients for a few days whilst in 4 cases no improvement in incontinence was noted. In addition, the patients developed fistula together with pain.

ii) The Vaginal Pessary

By incorporating electrodes in a vaginal pessary, Alexander and Rowan² (1968) devised an effective means of stimulating the levator ani muscle and part of the intrinsic urethral mechanism thus maintaining continence. The electrodes are wound on the pessary, a cable emerging from the vagina and being connected to a battery operated stimulator. In a case report, a patient who had been incontinent for 8 years was fitted with the device and after 3 months, although still incontinent on coughing, was dry enough not to need to change her clothing continuously. The stimulator is normally on and is only switched off to permit micturition.

Stanton⁶⁹ (1972) listed the disadvantages of the vaginal pessary as causing vaginal soreness and discharge, having a tendency to become dislodged, and the inability to insert it into a narrow vagina.

iii) Stimulator Implants

Electrical stimulation of the levator ani muscle near the bladder neck as a means to effect urinary continence was first used by Caldwell¹⁸ (1963).

Since striated muscle is being stimulated, the stimulating levels are much lower than those required to produce voiding when stimulating the detrusor muscle of the bladder. Typical stimulating parameters used are 4^v square pulses at a frequency of 20 cps and pulse widths between 1 and 4 mS (Caldwell et al²¹, 1968). Induction coils are used to transmit the stimulus through the intact skin.

Cooper²⁸ (1968) lists the criteria to be fulfilled in prospective patients as follows:

- a) Some innervated muscle in the pelvic floor must exist which will respond to stimulation.
- b) Continence must be of a dribbling or stress type due to low outflow resistance.
- c) Stimulation must raise the introvesical pressure at which voiding occurs.

In addition to the above criteria, Stanton (1972) includes:

- a) Satisfactory upper urinary tracts and absence of urinary reflux.
- b) Adequate bladder emptying.
- c) No uninhibited detrusor activity.

Methods used to locate the best possible site for electrode placement together with patient suitability (Caldwell et al²⁰, 1968) are:

- a) Stimulation via needles inserted through the perineum at different sites until perineal movement is noted.

- b) Recording urethral pressure profiles during coughing, straining and inhibited urinary flow. The site where the latter causes a sharp pressure rise is the section of urethra where stimulation is most likely to produce closure pressures.

Initially Caldwell¹⁸ (1963) used a stimulator to effect faecal continence in a patient who had been incontinent for 23 years by stimulating the anal sphincter. The patient regained complete control and after 3 months was continent without stimulation. The apparatus was then used to effect urinary continence in a patient who had been incontinent for 20 years. The patient remained dry with the aid of the stimulator.

Of the 8 failures reported by Caldwell et al¹⁹ (1968) in a group of 31 stress incontinent women who received stimulators, reasons for failure were given as 4 due to fractured electrodes, 2 due to migration or twisting of the implant, one due to sepsis, and one due to patient senility. No mention was made as to the length of time the stimulators had been implanted at the time of writing except to say that one woman was continent without stimulation one year after implantation.

Alexander and Rowan³ (1968) treated 8 patients with stress incontinence and 6 patients with 'neurogenic' incontinence using stimulator implants. In the former group, 50% success was achieved. Of the neurogenic cases, success was achieved in 5 out of 6 patients, all with upper motor neuron lesions. The one failure in this group, a patient with a lower motor neurone lesion, had no perineal contractions on stimulation during the operation to implant the device. The success achieved in the 'neurogenic' cases led Alexander and Rowan to believe that electrical stimulation of the external sphincter may also inhibit bladder contraction. One patient suffering from stress incontinence became continent after the operation to implant the stimulator without ever activating it thus indicating that the presence of the device also causes constriction of the urethra due to its presence so that both occlusion and stimulation are in effect being employed.

Stanton and Edwards²⁰ (1973) treated 18 children with urinary incontinence between 1967 and 1972 using stimulator implants. There were 5 failures, 5 successes and 8 cases where continence was improved. Problems encountered were electrode fracture, mal-positioning, pain, and infection.

Whilst having a higher success rate than devices used for electromicturition, stimulator implants for the restoration of continence rely on the continuous contractile response of muscle to electrical stimuli. Because of muscle fatigue, loss of contractile response occurs (Hald et al.⁴⁴, 1966) and could be the reason for the initial success followed by a return of incontinence experienced in many patients treated thus. Further research and time is required to ascertain the long term usefulness of these devices.

iv) Silastic Cuffs

Loss of contractile response in pelvic floor stimulation, and pain and draining sinuses due to prosthetic devices such as the Berry Procedure led to the development of cuffs which encircle the urethra and occlude it.

An external device for management of male urinary incontinence described by Citron et al.²⁵ (1972) consists of a hinge with a latching clasp affixed to a nylon band which is placed about the penis. The pressure surface of the hinge is of silicone rubber. The band is tightened sufficiently to prevent dislodgement whilst the device is deactivated. Occlusion and deactivation are performed manually by releasing the latching mechanism and by applying pressure on the penis until latching occurs respectively. The device is inconspicuous when worn. After a trial period of 3 days on two healthy volunteers no adverse effects were noted.

Timm⁷⁹ (1971) developed an inflatable cuff constructed of silicone rubber sheeting. When placed around the urethra near the urethrovesical junction, it could be inflated to occlude the urethra or deflated to permit micturition using stainless steel bellows. Experiments were conducted on dogs to determine minimum cuff pressures needed to occlude the urethra for continence restoration, and whether urethral tissue viability would be impaired by the device. Pain, tissue necrosis due to restricted blood flow, and fibrous tissue were absent for cuff pressures below 40 cm H₂O.

By attaching an RF powered solenoid to the bellows, Timm and Bradley⁸² (1971) could effect continence with a completely implantable device. Deflation of the cuff to permit micturition was achieved by activating an RF transmitter in the vicinity of the solenoid causing a solenoidal force to act on the bellows thus increasing their volume. This volume is supplied by the cuff thus deflating it. Whilst no fibrous tissue formation around the cuff was observed after 4 months in animal implants, they felt that the high cuff pressures required to maintain continence during stressful situations might impede blood flow in the urethra thus producing tissue necrosis. To circumvent this, Timm and Bradley suggested the combined use of mechanical urethral occlusion together with intermittent electrical sphincter stimulation during stressful situations.

Timm and Bradley⁸³ (1973) devised an artificial sphincter consisting of a reservoir containing fluid, a silicone rubber cuff with valves and two squeeze bulbs. The fluid is circulated from the reservoir down to the cuff and back when the right bulb (closed position) or left bulb (open position) are pressed respectively. The silastic cuff has an inner sheet thinner than the outer so that inner cuff pressure is transferred completely to the urethra. The valves consist of a ball and spring and permit flow only when the pressure on the ball side exceeds that on the spring side of the valve by an amount determined by the spring rate of the spring. The ball prevents flow in the opposite direction. Four months after implantation, the device was found to be encapsulated in fibrous tissue but no urethral stricture, discomfort or impairment of vascular supply to the urethra for cuff pressures below 40 cm H₂O was noted. The device was still effectual.

2.2

TREATMENT OF URINARY RETENTION BY RENDERING THE PATIENT INCONTINENT

The passage of urine depends on the balance between the expulsive force to which it is subjected and the outflow resistance which impedes its flow through the bladder neck and urethra. Surgical effort is directed at reducing outflow resistance. Methods used include transurethral resection of the bladder neck or Y-V plasty, external sphincterectomy, pudendal neurectomy and urinary diversion and are often successful when increased resistance is due to contracted pelvic floor muscles in the spastic phase of paraplegia (Ellis et al ³³, 1965). However, methods such as sphincterectomy decrease sexual potency (Hald ⁴³, 1969). Urinary diversion by means of an ileal conduit has complications such as stomal contracture, skin breakdown, residual urine, calculi, urinary tract infection, recurrent pyelonephritis and social embarrassment (Halverstadt ⁴⁸, 1971; Jagannathan et al ⁵¹, 1969; Wear et al ⁸⁴, 1967). Often reflex detrusor action is so weak that it becomes necessary to render the patient completely incontinent (Ellis et al ³³, 1965). Even if a completely reliable incontinence device were in existence, increase in intravesical pressure is still needed to ensure complete evacuation (Timm and Bradley ⁶⁸, 1971). Manual expression is difficult in obese patients (Hald ⁴³, 1969) and pharmacologic methods used to evoke detrusor contraction are not always satisfactory, especially in patients with atonic bladders (Chien et al ²³, 1973). Thus electrical stimulation may be useful in the treatment of flaccid neurogenic bladder (Smith ⁶⁸, 1966) and where urinary diversion is being considered (Halverstadt ⁴⁸, 1971).

Although 90% of paraplegics eventually become catheter free, in many the indwelling catheter has already contributed to significant morbidity and a method is needed whereby early removal of the catheter is possible (Stenberg et al ⁷², 1967).

Electrical stimulation has the initial advantage of producing immediate restoration of bladder function together with the elimination of urinary infection (Ellis et al ³³, 1965).

A further application of electrical stimulation is in the case of colonic bladder substitutes most of which ultimately fail due to infection resulting from their inability to empty completely (Merril and Markland ⁶⁰, 1972).

3

A REVIEW OF PROSTHESES IN URINARY RETENTION

All prostheses for overcoming urinary retention aim at increasing the expulsive force to which the urine is subjected to in the bladder, and the reduction of outflow resistance which impedes its flow. If the natural order of micturition can be mimicked, then the opening of the vesical neck will be sequential to contraction of the detrusor muscle. Methods used to achieve this fall into three categories viz. mechanical methods to contract the detrusor, nerve stimulation leading to detrusor contraction, and direct stimulation of the detrusor muscle itself.

3.1

MECHANICAL METHODS

51

In 1968 Jagannathan et al (1969) encased the bladders of dogs in double-walled casings of Dacron - reinforced silicone rubber. By inflating the interwall cavity, the inner wall collapsed onto the bladder increasing intravesical pressure sufficiently to cause voiding.

Immediately following surgery for implantation of the device, a good flow of urine was obtained together with complete bladder emptying. However, all subsequent testing produced only fair to poor emptying.

Autopsy revealed peritoneal adhesions, peritonitis, a marked decrease in bladder capacity, and a thickening of the bladder muscle together with the formation of fibrous tissue. Subsequent experiments on the effect of silicone rubber on the tissue of the bladder resulted in minimal tissue reaction. It was concluded that the reaction was therefore due to the shearing stress produced by the vigorous contractions of the bladder enclosed in such a relatively rigid casing. This indicates the use of such a prosthesis in cases where the bladder is atonic although the collapse of such a device onto the bladder may also be responsible in part for the serious complications developed.

Chien et al ²³ (1973) sutured steel discs to the dome, posterior and anterior walls of the bladder. An externally

placed electromagnet was used to provide the force and direction via magnetic induction to compress the detrusor. Whilst voiding was effected, omental adhesions, the development of vesical calculi, and in some cases tearing of the bladder due to the forces exerted on the discs by the external field, were experienced.

The above two methods, whilst producing voiding, are unphysiologic and hence seem to have little future practical value.

3.2

NEURAL STIMULATION

Dees ²⁹, in 1940-41, realizing that only the thickness of the rectal wall separates its lumen from the hypogastric plexus, decided to investigate the effect of electric stimulation on vesical contraction through an electrode in the lumen of the rectum. Since both sympathetic and parasympathetic fibres run from the hypogastric plexus to the bladder and prostate, this method avoids the complication of exposing the parasympathetic nerves to effect stimulation. Female cats were used. Whilst the bladder contracted on stimulation, voiding was effected in only one cat. Current spread to other nerves was observed together with pain. When tried in four patients, the method failed to produce voiding. Considerable pain experienced by one patient led to the termination of stimulation. The procedure was considered to have little clinical application and rejected for publication until 1967.

Burghale, Ichim and Demetrescu (1958 ¹⁶, 1959 ¹⁷) used electromagnetic induction to eliminate the need for wires between the pulse generator and the site of stimulation.

Using platinum cuff electrodes to stimulate the pelvic nerves in dogs, they obtained a rise in intravesical pressure with subsequent voiding. However, the urinary stream usually stopped after 10-30 seconds of stimulation.

Staubitz et al ⁷¹ (1966) used an implantable stimulator powered by batteries and activated by a magnetic switch to stimulate the pelvic nerves in dogs. Although most of the dogs died shortly after the operation to implant the stimulator, one dog survived for over 12 months. Electrical stimulation in this latter dog produced repeatedly good evacuation with no residual urine. Pain was noted during stimulation with intact hypogastric nerves. Stimulating voltages of up to 3^V were used.

Holmquist and Staubitz (1967) ⁴⁹ and Holmquist, Staubitz and Greatbatch (1967) ⁵⁰ had limited success with pelvic nerve stimulation. In those dogs that survived the postoperative period, nerve damage resulted if the electrodes were too tightly connected, or the ingrowth of tissue between the nerve and electrode took place if the electrodes were loose, thus decreasing the effect of the stimulus. Also, outflow resistance prevented micturition, most probably due to stimulus spread to the external sphincter.

Habib ⁴² (1967), by stimulating the fourth sacral nerve, produced voiding in two patients for 4 to 5 months. Simultaneous external sphincteric contraction also occurred together with chills, headaches and penile erections. He does not mention the efficiency achieved in voiding.

Hald ⁴³ (1969) used uni- and bipolar cuff electrodes to stimulate the second sacral root and pelvic nerves. In opposition to the above mentioned experimenters, he rejected the use of sacral and pelvic nerve stimulation as a means for treating neurogenic bladders for the following reasons:

a) In infranuclear lesion the motor nerve fibres to the bladder degenerate resulting in eventual total unresponsiveness to stimulation.

b) Infection at the electrode site is more likely to occur than in the case of direct detrusor stimulation.

c) Activation of the pudendal nerve because of current spread leads to excitation of the external sphincter with a resultant increase in urinary flow resistance.

d) Penile erection which usually occurs with nerve stimulation adds to the outflow resistance.

e) Spasms of the lower extremities and difficulty in breathing occur and can become very marked in cases where mass reflex tendency is already a problem.

f) In patients with incomplete lesions, pain due to electrode irritation is a problem.

The advantage of nerve stimulation when compared with stimulating the bladder muscle directly is that only an eightieth to one hundredth of the current is required to excite the nerve and hence obtain a comparable contraction of the muscle. However, current spread cannot be controlled by electrode design and placement as in the case of direct detrusor stimulation.

In 1972 Friedman et al ³⁷ used bipolar depth electrodes placed in the region of the central grey of the spinal cord to effect micturition in dogs with an overall success of about 60%. In one dog, urination was forceful accompanied by occasional defecation and no residual urine. Bladder contraction occurred without voiding in several cases due to contraction of the external sphincter. Spread of current also resulted in pain.

Extending the work of Friedman et al, Grimes et al ³⁹ (1973) used depth electrodes, mostly at the S2 cord level, to effect voiding in 5 patients. Success was achieved in 3 of the 4 cases now beyond one year post-implantation. In two of the cases external sphincterotomy had to be performed to improve the initial poor voiding obtained. Side effects noted are adductor spasms, pilo-erection, sweating, penile erection with occasional emission of seminal fluid, and sphincter spasm. These results are excellent when compared with the three long-term successes out of thirty-eight patients who received detrusor bladder stimulators.

3.3

DETRUSOR STIMULATION

The first attempt at evacuation of the urinary bladder using detrusor stimulation was that of Boyce et al¹⁰ in 1951, published in 1964 together with the results of W.F. Mc Guire (1964). Initially electrical stimulation using a Grass stimulator was performed on human patients during experiments to record the bioelectric action potential from the smooth muscle of the detrusor. The experiments were discontinued because of the severe pain occurring whenever the stimulus was sufficient to effect an increase in intravesical pressure.

In 1954 Mc Guire performed a series of experiments in an attempt to find the best type of electrode and its positioning on the bladder, voltage amplitude, waveform, duration and repetition rate to effect voiding. He found that the types of electrodes and waveforms used were not important but that the use of multiple electrodes gave a more uniform increase in intravesical pressure. Later Boyce et al noted that the electrodes should be completely buried in the detrusor to prevent distortion of the waveform.

Mc Guire and Boyce et al were also first in constructing and using a wholly implantable device thus obviating the danger of infection resulting from the use of wires passing through the abdominal wall. The receiver consisted of an induction coil coated with a plastic material of low tissue reactivity. Primary coils weighing 35 to 45 pounds were used. In 3 patients, implantation resulted in one complete failure due to severe pain with contractions of the adductor muscles of the thighs, partial success in one patient who could only void at high bladder volumes with resultant residual urine, and one success. This latter patient was able to void for 18 months using the stimulator. The stimulator then became ineffectual with accompanying pain.

The development of transistors enabled Boyce et al to construct a portable transmitter based on the findings of further experimentation on human bladders.

The earliest published reports on the use of a transmitter-receiver unit for evacuation of the neurogenic bladder by direct detrusor stimulation were those of Bradley et al ¹⁵ (1962) and Bradley et al ¹⁴ (1963). Their receiver was more sophisticated than that of Mc Guire, consisting of a tuned coil, a rectifying diode, and a capacitor and resistor for effecting biphasic pulses to prevent tissue necrosis. Stimulating electrodes used were stainless steel discs and tape electrodes implanted intraperitoneally. During stimulation, spread of current to neighbouring nerves and muscles was observed as well as pain in dogs with cauda equina lesions. They suggested that stimulus spread can be controlled by proper electrode location and design and that an extraperitoneal approach might eliminate pain. Important observations were that a sufficient area of muscle had to be stimulated to effect voiding, and that over-distention of the bladder and the use of an indwelling catheter reduced the response of the bladder to stimulation.

In 1965, Scott et al ⁶⁶, using large disc electrodes, produced complete bladder emptying in dogs by stimulating a 'trigger area' between the ureterovesical junctions thus suggesting that smooth muscle responds poorly to electrical stimulation, its response being mediated by its nerve network. An attempt to locate such a trigger area in humans failed. No intravesical pressure increase could be noted and voluntary urination could be interrupted by activating the receiver. This was obviously due to spread of current to the external sphincter and pelvic floor musculature.

In order to stimulate as large a mass of detrusor muscle as possible to lower stimulating levels, Ellis et al ³³ (1965) used braided stainless steel wire electrodes stitched into the wall of the bladder and insulated up to the point of entry into the muscle. They also introduced an important parameter

for measuring the effectiveness of stimulation viz. the volume of urine voided as a percentage of initial bladder volume. The transmitter used was also the first to receive its power from a battery source. Surge variations of stimuli were found to be more effective than the constant application of a voltage or current. Problems encountered by them included current spread and electrode breakage.

Markland et al ⁵⁸ (1966) implanted a stimulator in a patient and whilst an increase in intravesical pressure occurred, there was no voiding due to contraction of the external sphincter. Because of the poor condition of the detrusor muscle, it was thought that the pressure rise noted was due to contraction of the pelvic skeletal musculature.

In an attempt to decrease current spread, Bradley and Conway ¹³ (1966) designed bipolar electrodes. The first type consisted of two wires insulated from one another with metallic projections at regular intervals. Placed in close proximity, the two wires formed alternate positive and negative stimulating 'point' electrodes. A second form of bipolar electrode consisted of disc electrodes, the centre portion being insulated from the outer part, and a signal of opposite polarity being applied to each electrode.

Another method for decreasing the effect of current spread by eliminating urethral resistance was postulated by Hald and Mygind ⁴⁶ and Hald et al ⁴⁴ (1966). They applied a pre-stimulus fatiguing signal to the external sphincter thereby reducing its response to an electrical signal. Subsequent stimulation of the detrusor thus produced voiding. An implantable stimulator based on these findings was devised by Carstensen et al ²² (1970) and consisted of two independent circuits. The adjacent coils used were about 1.5 centimetres in diameter, their centres being displaced by about 4 centimetres from each other. No results are given as to the effectiveness of the apparatus.

Also in 1966, P.G. Lale⁵³ published a report on the mechanism of excitation of smooth muscle. He noted that current spread could be limited by the use of a grid of short wires having alternate polarity as the stimulating electrodes.

Problems related to electrical stimulation of the urinary bladder were listed by Montgomery and Boyce⁶² (1967) as the urge to defecate, abdominal cramps, penile erections and pain, all of which are due to current spread. Chou et al²⁴ (1967) found that no pain occurred if the spinal cord lesion was a complete one at the thoracic or cervical level, and if a complete cauda equina lesion was combined with a bilateral lower thoracic and lumbar sympathectomy.

Hald et al⁴⁵ (1967) suggested that treatment by electrical stimulation should be started as early as possible to avoid degeneration of the bladder musculature. After the implantation of stimulators in 3 patients with upper motor neurone bladders, reflex micturition occurred in two of them thus indicating that patients with lower motor neurone lesions are more suitable to this type of treatment. This view was supported by the results of Stenberg et al⁷² (1967) in 4 patients. Halverstadt and Leadbetter⁴⁷ (1968) achieved only one success in three patients with lower motor neurone lesions due to pain and sphincter spasm. It was thought that the placement of electrodes too near the bladder neck and pelvic nerve trunks was the cause. They also suggested insulating the electrodes from surrounding tissue by the use of a Silastic sheet.

Susset and Boctor (1967⁷³, 1968⁷⁴) used alternate positive and negative multiple electrodes in parallel with each other. The result was less tissue damage because of the diversion of current to the multiple electrodes and the minimal resistance so obtained. The stimulator eventually stopped working after 13 months due to rupture of 3 of the 8 electrode leads. The problem with electrodes that derive their energy from the same source is that current spread is maximized.

The electrodes are at the same potential at the same time and act as feedback paths for one another so that current spreads between them.

In 1959 Timm and Bradley⁸¹ suggested a further method for limiting current spread. In a series of experiments on dogs they attached three isolated pulse generators via electrodes to the bladder, two electrodes being positioned on the lateral ligaments on the ventral surface and the third one on the caudal- rostral midline of the dorsal surface. They then applied pulses simultaneously and sequentially to the three electrodes and found that with simultaneous pulsing, 10% of bladder contents was voided. By varying the periods between pulses, it was found that the amount voided was directly proportional to the period between pulses, with 100% of bladder contents being voided when these periods were equal. Two principles are involved here. Firstly since each source is electrically isolated from the others, current can flow between the two conductors in one electrode pair but not between electrode pairs thus limiting current spread. The second principle can be demonstrated as follows. Let the pulse rate during sequential pulsing be three times the rate during simultaneous pulsing. Consider a point equidistant from the three electrodes. The field generated at this point by each electrode is identical if the electrodes are the same and equal voltages are applied to them. Applying pulses simultaneously to the electrodes results in a field of triple intensity at this point, whereas sequential application gives single intensities three times as often. Since the surrounding tissue of concern contains rapidly accommodating nerve fibres with low stimulus thresholds, the increase in frequency of stimulus application to these nerves does not matter, but the lower current at this point is below the stimulus threshold of most of these fibres. Thus the stimulus is restricted to the volume surrounding each electrode.

In 1971 and 1973 Timm and Bradley^{82, 83} proposed a method to restore full volitional control of bladder function. It consisted of a volume sensor attached to the bladder, a bladder stimulator, and a device for incontinence control. The bladder stimulator consisted of an external transmitter and a number of miniature receiver-pulse generators attached to the bladder. The signal received by each implanted unit from the transmitter was used as a power source, activating an astable multivibrator in each receiver. Setting the rate of oscillation of the multivibrators to slightly different frequencies ensured nonsimultaneous application of pulses to the bladder. The electrodes they used consisted of two parallel conducting wires woven in a helical fashion between insulative spacing threads. These electrodes can easily follow bladder contour variations without interfering with the normal contractile function of the bladder. The electrodes were imbricated in the bladder wall so that only cells in the neural conduction system were excited.

A two channel sequential stimulator was used by Merrill and Markland⁶⁰ (1972) to electrically stimulate canine colonic bladder substitutes. Although current spread was not evident if stimuli below 15^V were used, it did occur when voltages of 20 to 30^V were used. Stimulation was painful and in unanaesthetized animals it resulted in contraction of the perineal muscles, intermittent voiding and incomplete emptying. This was thought to be due to volitional holding rather than current spread.

4. REASONS FOR INVESTIGATING THE RADIO FREQUENCY DETRUSOR STIMULATOR

4.1 CHOICE OF METHOD

The purpose of any prosthesis used to overcome urinary retention is to reproduce the natural sequence in micturition of detrusor contraction followed by relaxation of the urethrovesical junction. The lowest possible pressure needed to do this should be used otherwise additional problems such as refluxing of urine into the ureters will occur leading to possible renal failure.

Although the stimulating levels used in nerve stimulation to effect emptying of the neurogenic bladder are small when compared with those used in detrusor stimulation, this method was rejected for the following reasons:

a) Current spread still occurs because of the large diameter nerves being stimulated, their thresholds being much lower than the finer fibres found in the bladder musculature.

b) It is not possible to restrict this current spread by means of electrode design and positioning.

c) Nerve damage occurs easily because of the difficulty in fitting a nerve electrode so that it is neither too loose nor too tight.

d) Nerve stimulation presupposes intact neural pathways between the site of stimulation and the bladder. This is not always so.

The problems listed above plus those associated with mechanical methods used to effect voiding led the author to believe that the solution lies in direct detrusor stimulation.

4.2 BASIC REQUIREMENTS

The basic requirements of a stimulating device are that:

a) There be no protruding wires passing through the skin between the bladder and the stimulator since this is a

ready source of infection and distress.

b) The power source be external to the body so that the replacement of batteries does not necessitate any surgical operation.

c) The controls for activating the device be external to the body since, unlike a heart pacemaker which is in continuous use, a bladder stimulator is only used when there is a need to empty the bladder. Induction coils can provide the means for doing this.

d) The receiving circuitry be kept as simple as possible so that the size and weight of the implant are acceptable to the body.

e) The implant be embedded in an inert insulating substance.

f) The electrodes be flexible and able to withstand continuous movement, and also be as inert as possible to body fluids whether a current is passed through them or not.

g) The applied stimulus be biphasic in order to minimize tissue necrosis.

Added to these requirements must be the condition that current spread be kept to a minimum.

4.3

MINIMIZATION OF CURRENT SPREAD

Sequential pulsing as proposed by Timm and Bradley^{81, 82} (1969, 1971; see Section 3.3) limits current spread because of the reduced field intensity in areas distant to the electrodes. The use of isolated pulse generators to achieve sequential pulsing also prevents the current from spreading from one set of electrodes to another. However, as described in the previous chapter, the system they used to implement sequential pulsing of the bladder only pulsed sequentially at certain times. At other times the pulses appeared simultaneously or with continuously varying periods between them since each astable multivibrator was set to oscillate at a slightly different rate to that of its companions. Since voiding is most efficient when the periods between pulses are equal (Timm and Bradley⁸¹, 1969), the above system is not the best one possible.

It was thus decided to design a system to:

a) Supply biphasic pulses to the bladder in a continuously sequential manner.

b) Keep the implanted receiver as simple as possible, the complicated circuitry being in the external unit. This facilitates repairing the unit if necessary.

It was also decided to use helical dual electrodes as described by Timm and Bradley⁸² (1971) because of their good current restricting properties and their flexibility. Each electrode pair forms alternating positive and negative 'point' electrodes thus ensuring high electrical efficiency due to the high local rates of change of current, together with a rapid falling off of current at only a few millimetres from them. The nature of the weave (see Section 8.2 (ii)) allows the electrodes to follow bladder contour variations without interfering with the normal expansile and contractile function of the bladder.

By further insulating the electrodes from surrounding tissue with Silastic sheeting^{*}, current spread is kept to a minimum.

^{*} DOW CORNING CORP., MICHIGAN, USA. (SILASTIC SHEETING REINFORCED, cat. No.501-1)

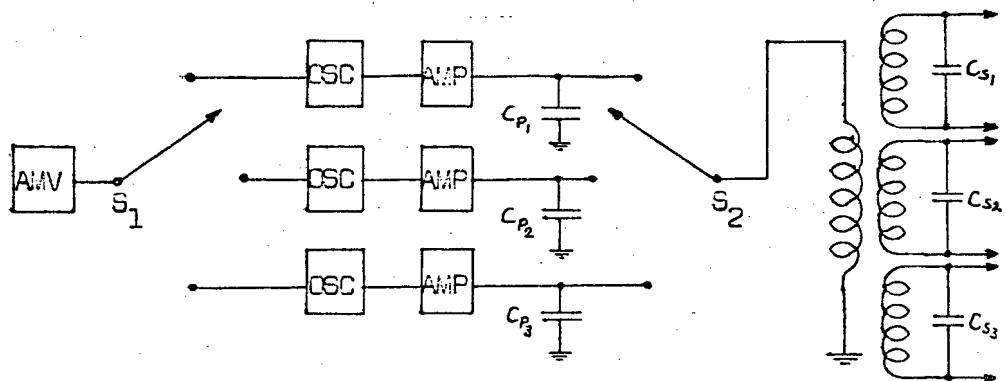
5 CHOICE OF SYSTEM

5.1 INTRODUCTION

Of the three systems considered by the author, the failure of the first led to the suggestion of the second system by R. Guelke⁴⁰. This was rejected in favour of the last system described here, which was developed with the aid of H. Melamed⁵⁹. This system is believed by the author to be a unique method for transmitting three simultaneous signals successfully to the simple type of receiver used. A block diagram of the system used appears in Fig. 4.

5.2 SYSTEM 1

This consists of one transmitting coil and three separate receiving coils each tuned to a different frequency as shown below:



Square pulses are generated which amplitude modulate a number of oscillators oscillating at different frequencies. Switches S_1 and S_2 are synchronized so that each channel is switched onto the primary inductance sequentially. Thus pulses with different carrier frequencies are generated in turn. The receiver consists of isolated tank circuits tuned to the frequency of each oscillator and leading to separate electrode pairs.

This system was rejected because:

a) It was found experimentally that each receiver 'locked' onto the next so that they tuned in at the same frequencies. At no time was it possible to isolate more than one channel from the other two when three sets of receivers were used. It was difficult to show this theoretically, but calculations showed that the reflected impedances from the coils were sufficient to completely alter the impedance of each tank circuit so that they resonated together.

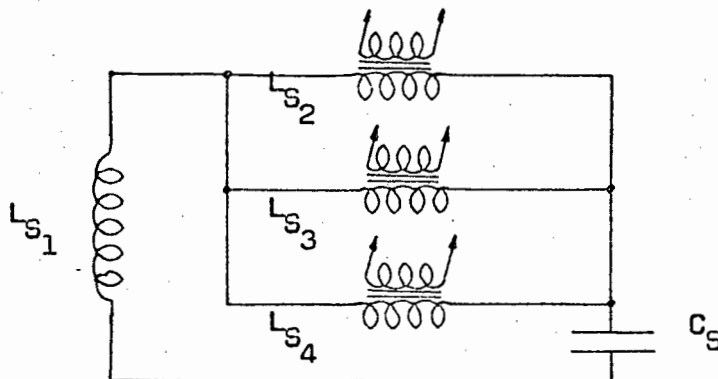
b) Since the switching circuit appears after the amplifiers it would have to carry large currents and voltages thus increasing the complexity of the transmitting unit.

c) Both switches need to be synchronized.

5.3

SYSTEM 2

The transmitter is as before. The receiver consists of one receiving coil, as shown below, in series with three parallel coils wound on cores. Because they are wound on cores, the parallel coils will have negligible flux leakage and hence interference between channels will not occur. Coupling between the large primary and secondary will be good.



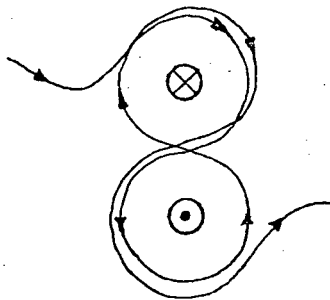
L_{S1} is small compared to L_{S2} , L_{S3} and L_{S4} so that they, together with the capacitor, determine the frequency of resonance. Each circuit is isolated from the other.

With respect to the transmitter this system has the same disadvantages as System 1. In addition, because of the limited space available for components in the receiver, it was felt that the additional three cores would increase the size of the receiver beyond practical limits. The cores would also increase the weight of the implant which should be kept as light as possible to avoid patient discomfort.

5.4 SYSTEM 3

If, in System 1, the fluxes induced in each secondary coil were to cancel with each other with respect to the other coils, then interference between channels would not occur.

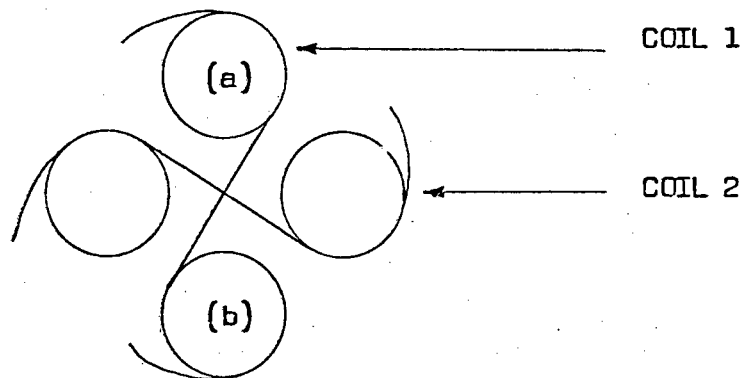
Consider the following:



If the coil is wound in the shape of a 'figure 8' then the flux induced in the one half will be in the opposite sense to the flux induced in the other half of the coil, provided that the primary is wound in the same shape.

If now another coil is wound in the same shape as the first one but at right angles to it, any flux that is produced by one coil will be zero with respect to the other coil due to its physical position. The twist in the coils allows both to be

placed in the same plane.



If a third coil is now wound in a circular fashion about the two 'figure 8' coils, then the flux that it will induce in side (a) of coil 1, say, will cancel the flux it induces in side (b) of coil 1, and vice versa (see Fig. 3).

Thus it is possible to have three sets of coils close together and completely isolated from one another provided that:

a) The primary coils are of the same shape as those of the secondary for each set.

b) The coil halves of each coil set are identical in size, shape and inductance.

c) Each coil side is wound in the opposite sense to its partner in each 'figure 8' coil.

d) The two 'figure 8' coils be set at right angles to each other and the circular coil encompasses each of the other two coils in the same way.

e) The primary coils are positioned so that each coil is directly over each secondary coil.

5.5

ALIGNMENT OF COILS

The obvious disadvantage of this system is condition e) above since whilst the coils can be constructed to some fair degree of accuracy, it may not be as easy to position the primary coils over those of the secondary which lie inside the body. Meyers et al ⁶³ (1969) describe a cup in which the external



Fig. 3 WINDING PATTERN OF COILS: PRIMARY COILS

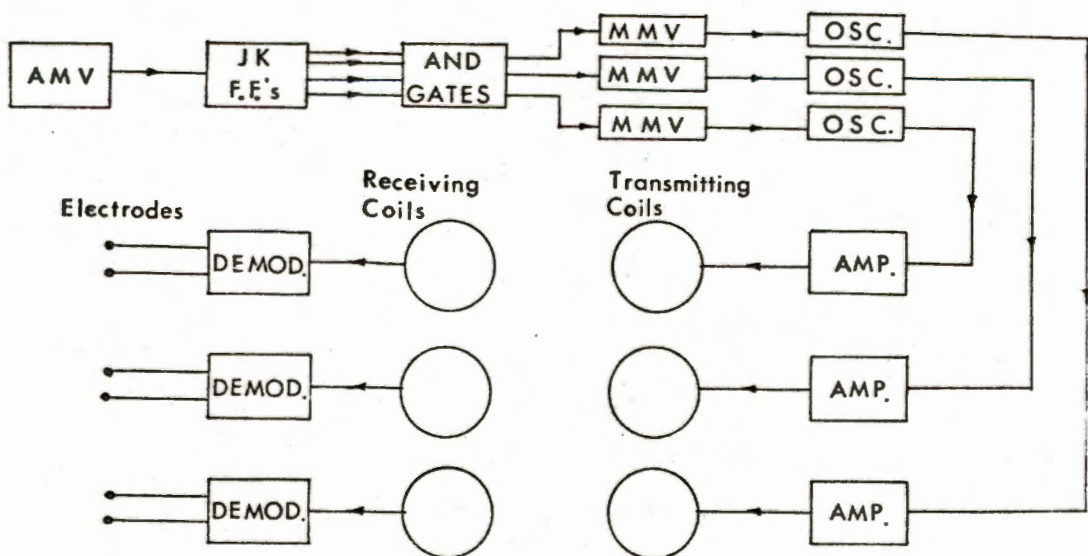


Fig. 4 BLOCK DIAGRAM OF RF SEQUENTIAL BLADDER STIMULATOR

coil lies. Since an internal coil will cause a bulge in the skin, the external cup can be fitted over the bulge thus preventing lateral movement of the implant and promoting closer coupling of the two units. If now the units are of a non-circular shape, when the external cup is fitted over the bulge produced by the internal unit, the correct alignment between the sets of coils will be realized. Thus the system is a feasible one.

By further tuning of each coil-set to different frequencies, any slight misalignments will have a minimum effect.

6 ELECTRICAL REQUIREMENTS FOR URINARY BLADDER STIMULATION

6.1 INTRODUCTION

Besides electrode configuration described in the previous chapters, parameters such as pulse length, pulse rate, pulse amplitude and polarity, bladder impedance and electrolytic effects must be considered.

6.2 PHYSIOLOGICAL ASPECTS

P.G. Lale⁵³ (1966) drew the following conclusions from a study of the physiology of, and the mechanism of excitation of smooth muscle:

a) The depolarizing potential which diminishes the resting potential across the membrane of the muscle fibre thus causing contraction of the muscle, is created by the change in field strength with distance and not by the field strength itself.

b) With 'point' electrodes buried in the smooth muscle and stimuli of a few volts, only nerves lying within one or two millimetres of the electrodes will be stimulated. For larger nerves the distance may increase to ten millimetres.

c) Excitation normally only occurs around the negative electrode with pulses longer than half a millisecond not being much more effective.

d) For excitation to occur around the positive electrode, pulses of higher amplitude or duration of more than two milliseconds are required.

e) If the rise time of the potential is tens of milliseconds, excitation of the nerve will not occur due to accommodation. Therefore pulses of a few milliseconds or less must be used.

f) The lowest frequency of stimulation needed to produce sustained contraction in smooth muscle is less than one per second.

6.3

STIMULATION PARAMETERS

Because the optimum pulse width varies according to the state of tonus of the bladder, it is difficult to specify a specific value. The following is a list of pulse width and rate used by previous investigators:

1-5 mS	20-25 pps	(Bradley et al ¹⁴ , 1963)
1.5 mS	20 pps	(Ellis et al ³³ , 1965)
4 mS	20 pps	(Hald et al ⁴⁵ , 1967)
1 mS	20 pps	(Susset & Boctor ⁷³ , 1967)
5-10 mS	10 pps	(Wear et al ⁸⁴ , 1967)
4 mS	20 pps	(Stenberg et al ⁷² , 1967)
4 mS	20 pps	(Halverstadt & Leadbetter ⁴⁷ , 1968)
4-5 mS	30-40 pps	(Carstensen et al ²² , 1970)
0.3-10 mS	20 pps	(Talibi et al ⁷⁶ , 1970)
1 mS	20 pps	(Merril & Markland ⁶⁰ , 1972)
1 mS	20 pps	(Timm & Bradley ⁸³ , 1973)

Nearly all investigators used a frequency of 20 pulses per second but varying pulse widths. Talibi et al ⁷⁶ (1970) explain that the optimal pulse rate depends only on the frequency response of the system 'nerve-muscle fibril of the bladder' and is independent of the nature, configuration and insulation of the electrodes. However, for constant voltage stimulation, the optimal pulse width depends on electrode configuration and current spread.

For the type of electrodes employed (see Section 4.3), it was decided to use a pulse rate of 20 per second and a pulse width of 1 mS (Timm & Bradley ⁸³, 1973; Mentor Bladder Stimulator^{*}).

6.4

ELIMINATION OF DIRECT CURRENT

Because excitation occurs around the negative electrode, negative monophasic pulses are used. Electrolytic effects are

* MENTOR BLADDER STIMULATOR : MENTOR CORP., NEW YORK, USA.

minimised by the incorporation of a decoupling capacitor in series with one of the stimulating electrodes. Biphasic pulses are produced and there is no net flow of DC current.

6.5

BLADDER IMPEDANCE

The impedance of the bladder depends upon its size, the volume of fluid it contains (Shabazian⁶⁷, 1969; Talibi et al⁷⁶, 1970), overdistention (Bradley et al¹⁴, 1963) and the area of electrode in contact with the musculature (Susset & Boctor⁷³, 1967; Bradley et al¹⁴, 1963).

Talibi et al⁷⁶ (1970) measured the impedance of the bladder and found it to approximate a resistor in series with a parallel capacitor-resistor arm. The series resistance ranged in value from 42 ohms to 155 ohms with an average of 118 ohms in 16 dogs. Mentor Corporation designed a stimulator to work with a load of 50 ohms, whilst Susset & Boctor⁷³ (1967) found the bladder impedance to vary from 75 ohms to 100 ohms depending on the number of electrodes used. Hald⁴³ (1969) in a treatise on neurogenic dysfunction of the bladder mentions the following investigators and bladder impedance measured by them:

Alexander and Rowan ¹ (1965)	70-370 ohms
Kantrowitz & Schamaun ⁵² (1964)	183 ohms
Bradley, Chou & French ¹² (1963)	35-100 ohms

Using either two or four electrodes, Hald measured a bladder impedance of 155-190 ohms and 53-140 ohms in dogs respectively. A value of 227 ohms was measured using two electrodes in a patient.

In an attempt to locate the optimal sites for electrode placement, the author constructed a catheter-type probe with retractable platinum wire electrodes. Using human subjects the probe was passed through the urethra into the bladder, and with the aid of a cystometer, placed at various sites on the bladder wall. Square pulses of constant current (27 mA) were used.

Recordings of stimulus voltage and current together with intravesical pressure were made.

Recorded impedances ranged from 70 ohms to over 500 ohms with variations in impedance also occurring between various sites on the bladder as shown below:

SITE	IMPEDANCE (ohms)
Between ureters	167
Bladder neck	450
Roof	192
Lateral median	400
Lateral superiorly	212

The experiments were terminated because it was impossible to ensure that the surface area of electrode in contact with the musculature remained constant. As stated above, the bladder impedance was found to vary depending on the number of electrodes used. Timm & Bradley⁸⁰ (1968) measured impedances ranging from 125 ohms to 533 ohms using bipolar electrodes. Impedance variation was due not only to varying ratios of outer to inner area of the disc electrodes, but also due to variation of stimulus intensity.

6.6

POWER REQUIREMENTS

Timm & Bradley⁸⁰ (1968) found that a current density of 3 to 5 mA per cm² is required to evoke contractions, that pulse amplitudes as high as 30^V have been required to obtain complete evacuation of bladder contents, and that 1 watt is needed at the output of the stimulator (Timm & Bradley⁸², 1971). Other investigators who found an output of 1 watt necessary to effect emptying are Ellis et al³³ (1965), Hald et al⁴⁵ (1967) and Susset & Boctor⁷³ (1967).

6.7

DESIGN PARAMETERS

It was thus decided to design a stimulator which would deliver 1 watt to a 100 ohms load, the capacitive part of the bladder being incorporated in the large capacitor placed in series with the output lead used to produce biphasic pulses. The pulse width was chosen as 1 mS and the pulse rate at each electrode pair was chosen as 20 cps.

7 THE RADIO FREQUENCY BLADDER STIMULATOR

7.1 THE LOGIC CIRCUITRY

The function of the logic circuitry is to supply each of the three oscillators with a train of modulating pulses in such a way that each oscillator produces bursts of oscillation for a fixed time and at a fixed rate of bursts. If the first channel produces a pulse at time $t=0$, say, and a second pulse at time $t=t_1$, then the second channel must produce a pulse at time $t=t_1/3$, and the third channel at time $t=2t_1/3$ so that the periods between the appearance of pulses at the three outputs are equal.

A complete diagram of the circuit appears in Figure 15, and the output waveforms of the various stages are shown in Figure 16. Details of the design are given in Appendix G.

i) Astable Multivibrator (AMV)

Specifications:

Frequency	60 Hz
Output pulse duration	8.33 mS

The pulse generator consists of a Schmitt trigger (SN7413N) with an RC timing circuit which converts it into a freerunning multivibrator. The frequency is adjusted by varying the timing capacitor.

ii) Dual JK Flip Flops

The two JK flip flops (SN7476N) are gated by the output of the AMV in such a way that a logical '1' appears in turn at three different pairs of outputs for each three input pulses. The sequence is then repeated.

iii) AND Gates

The SN7408 quadruple two-input positive AND gate is used. Each of the three pairs of outputs from the JK flip flops is fed to the two inputs of an AND gate. Thus one pulse will appear at each output of the three AND gates for each pair of simultaneous pulses at the inputs.

iv) Monostable Multivibrators (MMV)

Specifications:

Output pulse duration 1 mS

The output of each AND gate is used to trigger three MMV's. The SN74121N MMV is used. Since the output pulse widths of the stage are 16.6 mS, the MMV's are used to adjust the pulse widths to the specified duration. This is achieved by varying the resistor of an external timing circuit on each one-shot multivibrator.

7.2

COUPLING COILS

Radio-frequency (RF) transmission of energy through the intact skin to an implanted receiver abolishes the need for having protruding wires passing through the skin, an essential requirement since this is a ready source of infection and distress. The power source is then external to the body so that battery replacement does not necessitate any surgical operation. Unlike most heart pacemakers, the bladder stimulator is used intermittently. The use of coupled coils enables the stimulator to be activated at will. Also since the stimulator is controlled externally, pulse width, rate and amplitude can be adjusted to effect optimal voiding conditions in each individual.

This section describes in detail the design of the coupling coils. A complete circuit diagram of the radio-frequency circuit is given in Fig. 5.

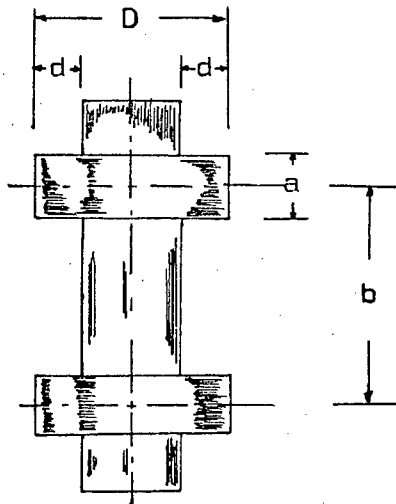
i) General Considerations

S.W. Amos⁴ (1943), using Reyners formula for inductance

$$L = \frac{0.2N^2D^2}{3.5D+81} \times \frac{D-2.25d}{D} \mu H$$

derived a formula for the coupling coefficient between two similar coils:

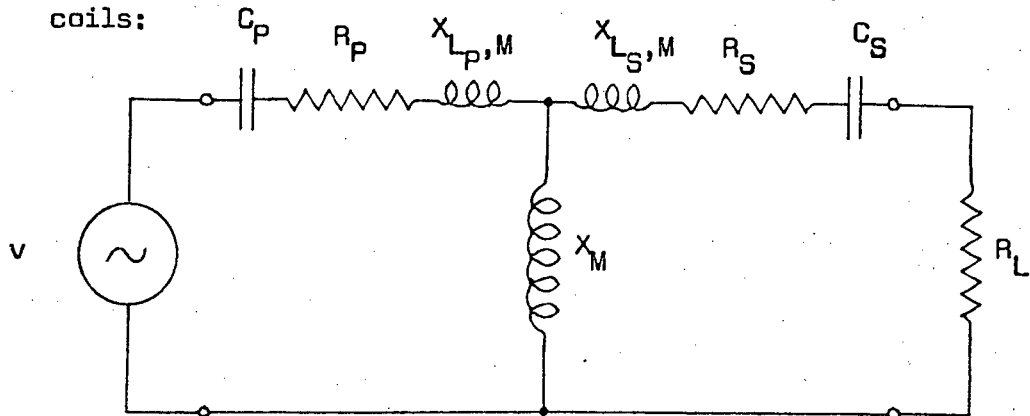
$$K = \frac{\left(1 + \frac{2.3a}{D}\right)}{\left(1 + \frac{2.3b}{D}\right) \left(1 + \frac{2.3c}{D}\right) \left(1 + \frac{2.3e}{D}\right)}$$



where D = overall coil diameter
 d = depth of winding
 a = length of winding
 b = separation between coils
 N = number of turns
 $c = b - a$
 $e = b + a$

Thus the larger the diameter of a coil, the greater the coefficient of coupling will be between two similar coils. Also the larger the number of turns, the greater the inductance of each coil will be and hence the mutual inductance.

Consider the following equivalent circuit for two coupled coils:



At resonance, the voltage appearing across wM will appear across R_L , and most of the power will be dissipated in R_L if:

a) $R_L \gg R_S, R_P$

b) $wM \gg R_L$

Now $M = K \sqrt{L_P L_S}$ so that for large M , L_P and L_S , the primary and secondary inductances respectively, must be large. Thus the number of turns and the diameters of each coil must be as large as possible. The size of the coil is limited by the size of the receiver, and the number of turns is limited by the gauge of wire needed to carry the required current and its RF resistance which increases with decrease in gauge.

Because of the difficulty of calculating the RF resistance by computer, it was decided to design the coils using an experimental rather than a theoretical approach.

ii) Choice of Coil Dimensions

Langford-Smith⁵⁴ (1963) states that maximum inductance occurs when:

a) $l/c = 1$

b) $c/a = 0.662$

where

l = length of winding

c = radial depth of winding

a = radius of coil to centre of winding

The outer diameter of the small windings was chosen as 2 cm, the maximum possible diameter, and the inner diameter was chosen as 1 cm so that:

$$c = 0.5 \text{ cm}$$

$$a = 0.75 \text{ cm}$$

$$l = 0.6 \text{ cm}$$

$$l/c = 1.2$$

$$c/a = 0.666$$

which approximates the conditions for maximum inductance.

The outer diameter of the large circular coils was chosen as 6 cm, the length and radial depth of the winding being the same as those of the small windings.

iii) Choice of Frequencies

The stimulating pulses are transmitted by means of carrier waves.

Takashima ⁷⁵, (1966) showed that whilst the absorption of electromagnetic energy by alcohol dehydrogenase molecule occurs in the neighbourhood of 1 MHz, and by DNA in the 1 KHz region, the energy of radio waves in these regions is too small by at least a factor of 10^7 when compared with the minimum energy required to break the weakest bond viz. the hydrogen bond. Thus radio waves in this frequency range do not have a nonthermal effect on the structure of molecules.

Besseling et al ⁸ (1965) used frequencies in the order of 30 MHz to heat blood, and Mackenzie et al ⁵⁷ (1967) found that frequencies below 10 KHz cause pain and discomfort.

Some carrier frequencies used for RF bladder stimulators are listed below:

1 MHz	(Bradley et al ¹⁴ , 1963)
300 KHz	(Mentor Bladder Stimulator*)

*MENTOR BLADDER STIMULATORS: MENTOR CORP., NEW YORK, USA.

100 KHz	(Halverstadt & Leadbetter ⁴⁷ , 1968)
100 KHz	(Susset & Boctor ⁷³ , 1967)
100 KHz	(Hald et al ⁴⁵ , 1967)

Since (from 7.2(i)) ωM must be large, the highest possible frequency must be used which will not decrease the Q factor of the coils unduly by increasing their RF resistance.

To minimize the possibility of interference from radio broadcasting stations, a frequency of below 200 KHz should be chosen. Also, the Decca Navigation system uses a carrier frequency in the region of 80 KHz.

Initially a carrier frequency of 190 KHz was chosen for the first channel, 160 KHz for the second, and 130 KHz for the third channel. When the variable capacitor boxes were replaced by available capacitors, the frequencies used were 169.4 KHz, 143 KHz and 112 KHz for the first, second and third channels respectively.

The following table illustrates the amount of 'cross-talk' between channels:

COIL 1	COIL 2	COIL 3
$P_o = 1.44 \text{ W}$	$P_o = .0256 \text{ W}$	$P_o = .0324 \text{ W}$
$P_o = .0025 \text{ W}$	$P_o = 1.44 \text{ W}$	$P_o = .0784 \text{ W}$
$P_o = .0049 \text{ W}$	$P_o = .0032 \text{ W}$	$P_o = 1.44 \text{ W}$

Since about 1 watt is needed to effect contraction of the urinary bladder, the power levels at the two electrode pairs due to 'cross-talk' from the 'ON' electrode pair are far below that required to produce contraction. Thus sequential pulsing has been fully realized.

Exciting each coil separately and rotating the receiver by 90° with respect to the transmitter produced the following results for the same excitation as the above table:

EXCITED COIL	COIL 1	COIL 2	COIL 3
1	-	$P_o = .01157 \text{ W}$	$P_o = .0324 \text{ W}$
2	$P_o = .01224 \text{ W}$	-	$P_o = .0784 \text{ W}$

Thus tuning each channel to a different frequency reduces interference between channels.

iv) Design of the Coils

Having chosen the dimensions of the coils and the carrier frequencies, it is now possible to calculate the inductance, coupling coefficient for a certain separation, the RF resistance⁶ and hence the optimum series load and efficiency of each coil set.

The RF resistance of a coil depends upon the skin factor and proximity factor which increase with decreasing wire gauge, and the DC resistance which decreases with decreasing wire gauge. Thus it is possible to find a certain wire gauge which will make the RF resistance a minimum. S.W.G. 40 wire was found experimentally to be the optimum wire gauge for the chosen dimensions of the 'figure 8' coils. The RF resistance of each coil should be small when compared with the series load (secondary) or the reflected impedance into the coil (primary) so that most of the energy is dissipated in the load and not the coil. Stranded wire is used so that the coil can tolerate the voltage and current levels required. Litz wire of the required gauge was not available so the coils were constructed of stranded wire wound by hand.

The number of turns is calculated from the dimensions of the coils and the wire gauge, and hence the inductance and coupling

coefficient (see Section 7.2(i)). The mutual inductance can thus be calculated. The RF resistance of each coil is calculated from a chart.⁶

Appendix A shows the derivation of an expression for the efficiency of transport of power between two sets of coils, and Appendix B, the optimum series load for maximum efficiency at a set frequency and coil spacing.

The principle of the auto-transformer is used to match the impedance of the bladder to the optimum series load since all that is required is a tapping on the secondary coil with no additional components. Appendix C describes the transformation of a series load into a parallel one, and Appendix D, the required turns ratio of the auto-transformer.

v) Choice of Coils

a) 'Figure 8' coils.

Various coils were constructed as shown in the table below. Coil pair 1 had dimensions:

$$D_o = 1.8 \text{ cm} \quad l = 0.7 \text{ cm} \quad D_i = 1.2 \text{ cm}$$

where

$$D_o = \text{outer radius of coil}$$

$$D_i = \text{inner radius of coil}$$

$$l = \text{length of winding}$$

Coil pairs 2 to 6 had dimensions:

$$D_o = 1.9 \text{ cm} \quad l = 0.6 \text{ cm} \quad D_i = 1 \text{ cm}$$

Coil 5 is a modification of coil 4 which, because of the high impedance reflected into the primary and the high voltage thus needed to produce 1 watt at the output resulted in breakdown of the insulation. Instead of using 900 turns, 7 strands of 130 turns per coil side are used, the voltage and current thus decreasing by a factor of 7, and the inductance and resistance by a factor of 49. The Q factor and coupling coefficient and hence the efficiency remain constant.

Coils with cores were considered but suitable iron cores were not available.

TABLE OF 'FIGURE 8' COILS CONSTRUCTED AND TESTED

COIL	R_{DC} (ohms)	R_{RF} (ohms)	f (kHz)	S.W.G.	Turns per coil side	L (mH)	M (μ H)	R_L (ohms)	% Efficiency	Input Power (Watts)	Output Power (Watts)	Comments
1	4	44.6	130	38	281	2.37	153	200	35.2 27.4	4.1	1.123	Efficiency decreased with increase in power-breakdown of insulation occurred
2	3.235	310	125	28	223	.332	43.3	100	9.76			
3	12.1	48	120	34	340	2.68	39.3	300	41.6	1.6	0.666	0.6 cm apart
4	130	210	120	40	900	22.7	1182	1000	58.1	0.2	0.1163	Breakdown of insulation occurred at higher power levels
5	2.54	7.81	190	7/40	130	.403	23.38	30	53.9	5.48	2.95	1.2 cm between coils
6	.079	-	190	70/40	13	.0052						

Since a parallel tuned circuit is used on the primary side, the load the amplifier 'sees' at resonance is the effective parallel resistance of the primary. Using coil pair 5 this resistance is about 5 Kiloohms. In order to deliver 5 watts to this load, a voltage of about 158^V is needed. Since this is not practical, the primary of coil pair 5 was reconstructed (viz. coil 6 in the table).

Both pairs of 'figure 8' coils are identical except for the tappings on each coil since different frequencies are used.

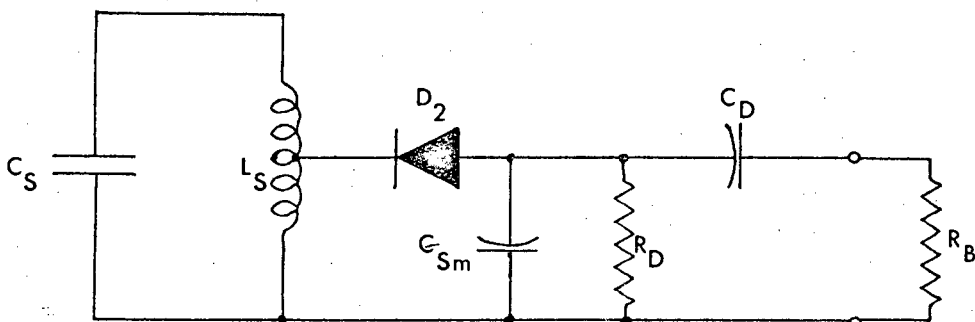
b) Outer Coil.

The secondary coil was wound with 130 turns, again using seven strands of S.W.G. 40 wire, whilst the primary coil was wound with 13 turns using seventy strands of S.W.G. 40 wire.

Specimen calculations for one coil appear in Appendix F together with a table comparing the theoretical and experimental properties of the coils.

vi) The Receiving Circuit

Each receiving circuit consists of a receiving coil parallel-tuned by a capacitor, a rectifying diode and smoothing capacitor, and a decoupling capacitor with a leakage resistor as shown in the circuit below:



A smoothing capacitor is used to demodulate the stimulating pulse. The equivalent resistance seen by the load can be calculated as shown in Appendix E, and the tapping on the secondary coil adjusted accordingly.

To minimize tissue electrolytic effects and to prolong electrode life, it is necessary that an equal amount of charge be passed in both directions through the detrusor muscle. This is achieved by placing a capacitor in series with one of the output leads. When a pulse is present the capacitor will charge up with a time constant equal to the product of capacitance and bladder resistance. During the period when no pulse is present, the capacitor discharges through a parallel resistor thus producing a biphasic waveform with zero average DC output voltage.

7.3

THE RADIO FREQUENCY POWER AMPLIFIERS

Each amplifier consists of a common emitter power stage, Q_6 , driven by a common collector amplifier, Q_5 (see Figure 5). This type of amplifier was used as the power stage in RF endocardial pacemakers by Mac Donald⁵⁶ (1965) and Astrinsky⁵ (1968). A full description of the performance of this type of amplifier is given by Astrinsky.

The AC carrier is fed through capacitor C_6 and clamped to earth by diode D_1 . The transistors conduct when the base to emitter turn-on voltage is reached and then only on the positive peaks of the input signal which exceed this voltage. Thus besides its leakage current, the output stage draws no current from the supply when no signal is present. The amplifier thus operates in the Class C mode and under normal loading conditions it is driven hard into saturation. As the amplitude of the input signal is increased, the conduction angle increases and in the limit the amplifier operates in the Class B mode.

7.4

THE CARRIER OSCILLATORS

A separate carrier oscillator is used for each channel.

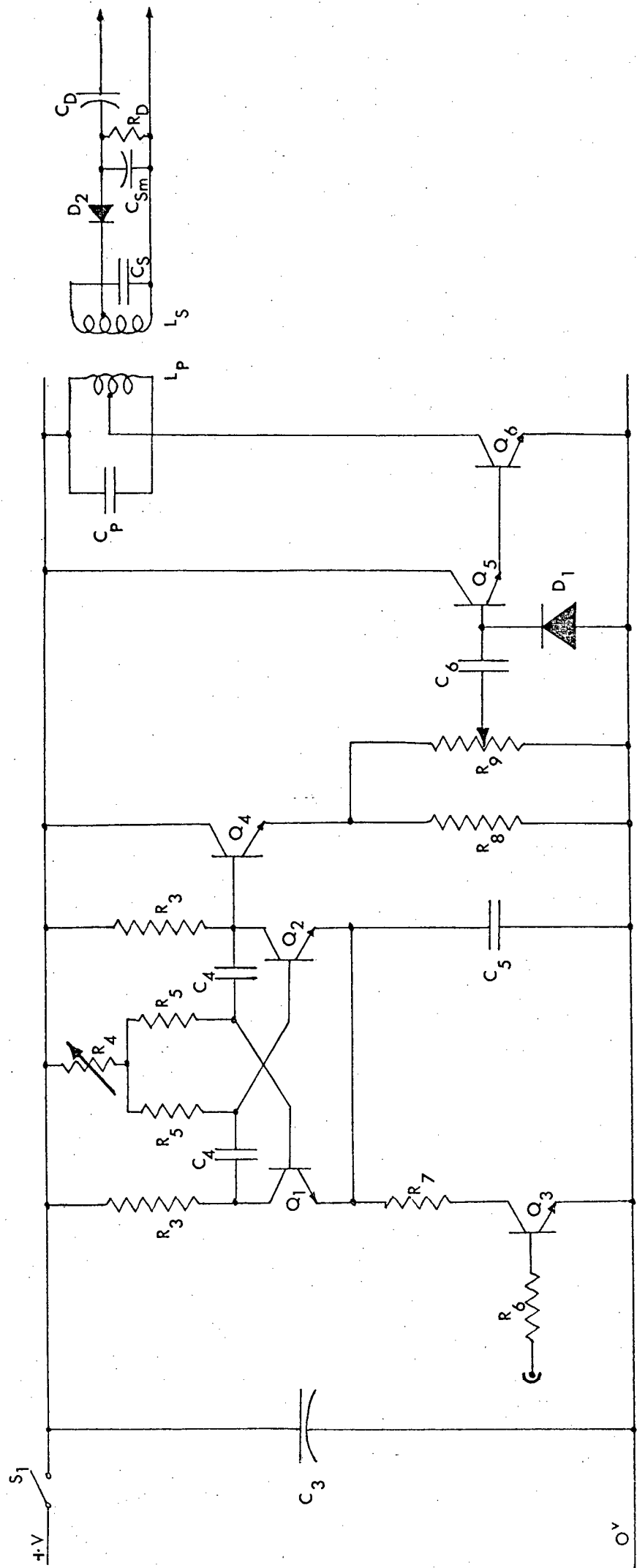


Fig. 5 ONE CHANNEL SHOWING OSCILLATOR, AMPLIFIER, TRANSMITTER AND RECEIVER

Combining the oscillators and amplifiers into one unit would have meant energy waste and a reduction in efficiency.

Astable multivibrators are used (see Figure 5) since no transformer is needed resulting a reduction in weight and physical size of the circuit.

The astable circuit has two states, both of which are quasi-stable. It requires no external triggering signal to make successive transitions from one quasi-stable state to the other. A description of this basic circuit is given by Milman & Taub⁶¹ (1965). The frequency of oscillation is determined by the product of timing resistors R_5 and capacitors C_4 . By varying R_5 (using R_4) it is thus possible to adjust the frequency.

Each oscillator is gated by a monostable multivibrator (see Section 7.1(iv)) via resistor R_6 and transistor Q_3 . When a modulating pulse is present at the base of Q_3 , Q_3 will saturate, the emitters of Q_1 and Q_2 will be almost at earth potential and the astable circuit will oscillate. When no pulse is present, Q_3 is in the cutoff region thereby causing transistors Q_1 and Q_2 to saturate thus forcing the oscillations to stop.

To reduce loading of the oscillators by the amplifier stages, an emitter-follower, Q_4 and R_8 , is used. Amplitude control of the output is effected by varying the drive to the amplifier stage via variable resistor R_9 .

7.5

THE POWER SUPPLY

If the stimulator is to be powered from the main line supply, this necessitates the availability of a suitable power outlet wherever the patient may be thus restricting free movement and possibly causing social embarrassment. It was therefore decided to use batteries as the power source.

Two types of batteries were considered: the mercury and nickel-cadmium (NiCd) cells. Both types maintain a constant output voltage during discharge and they are also readily available.

F.E. Whitway⁸⁵ (1970) in a review of power sources in bioelectrical engineering writes that whilst mercury cells have better power to weight ratio and power to volume ratio than secondary cells such as the NiCd battery, primary cells become uneconomical when used in other than low power applications. As an example he states that the total cost per year using rechargeable NiCd cells with a capacity of 900 mAh and a power consumption of 0.32 W is £9. However, dry mercuric oxide cells with a capacity of 1000 mAh and the same power consumption, cost £488 per year. Since the batteries need to supply 7 W, or 0.7 Wh per day, it was decided to use rechargeable NiCd batteries as the power source.

In a review of NiCd batteries (TEKSCOPE⁷⁷, 1969), the sealed cell is preferred to the unsealed type. It uses a minimum amount of electrolyte, can tolerate overcharging by dissipating the energy as heat, is efficient at high discharge rates and requires little maintenance besides ensuring that the battery does not discharge below the end point voltage when cell damage may occur.

Eight 1.2^V, 450 mAh penlight NiCd batteries are used in series. The N-450AA* has a charging time of 14-16 hours and battery chargers (NC-450 CADNICA*) are inexpensive and can recharge four batteries simultaneously.

Since peak currents of upto 1 A will be demanded from the batteries, a large capacitor, C₃, is placed across them to reduce peak loading (see Figure 5).

Because the integrated circuits require a supply voltage of about 5^V, the L005** voltage regulator is used.

* Manufactured by SANYO ELECTRIC CO. LTD., JAPAN.

** Manufactured by FAIRCHILD

Specifications of the L005 are:

Maximum input voltage	20 ^v
Maximum output voltage	5.25 ^v
Standby current	9 mA
Maximum current output	> 600 mA
Ripple rejection	62 db typical

8

DETAILS OF CONSTRUCTION

The complete unit is shown in Figure 1.

8.1

THE EXTERNAL APPARATUS

The electronic components are mounted on two pieces of perforated insulating board* with copper strips on the under surface. A high component packing density is used to ensure as small a unit as possible. The boards are housed in a perspex case such that they can be slid out to effect repairs as illustrated in Figure 6. By removing the top of the case it is possible to adjust the frequency and pulse width of each channel by means of trimming potentiometers.

The batteries are housed in penlight battery holders so that they can be easily removed for recharging, and the case is connected via a cable to the transmitting coils as shown in Figure 7. Thus the apparatus can be carried in a pocket while the transmitting coils are placed in position over the receiver. The unit is thus inconspicuous when worn.

The logic circuitry chips are in holders to facilitate easy replacement in case of failure. The emphasis in design has been on easy accessibility to all parts of the transmitter whilst there are no controls on the outside for the patient to mishandle. A conveniently placed button switch allows the patient to initiate and terminate stimulation.

The coils are wound on perspex formers embedded in a perspex sheet which has the same shape as the encapsulated receiver to ensure correct alignment of the two units (see Figure 3).

Coil Housing

Dimensions:	7.4x6.8x1.5 cms
Cable length:	45 cms
Total weight of transmitter:	628.9 gms

* Veraboard

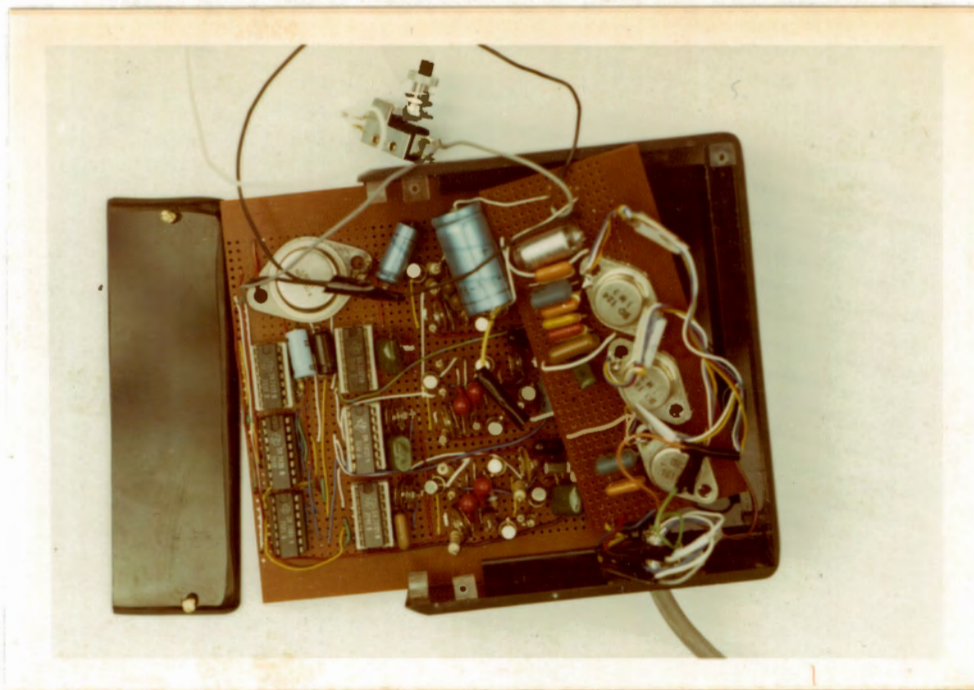


Fig. 6 TRANSMITTER ILLUSTRATING REMOVAL OF WORKING PARTS
FROM CASING AND HIGH DENSITY PACKING OF COMPONENTS



Fig. 7 TRANSMITTER CASE WITH LID REMOVED, BATTERIES AND PRIMARY
COILS

8.2

THE IMPLANTED RECEIVERi) Construction

The receiver consists of two coils wound on four perspex formers, and a third coil wound in a circular fashion about these. The formers are embedded in semi-circular perspex sheets. All the electronic components are either inbetween the coils or next to them as illustrated in Figure 8.

All leads were cleaned with acid prior to soldering to ensure good connections.

Dimensions prior to encapsulation: 6x6x0.9 cms

ii) The Electrodes

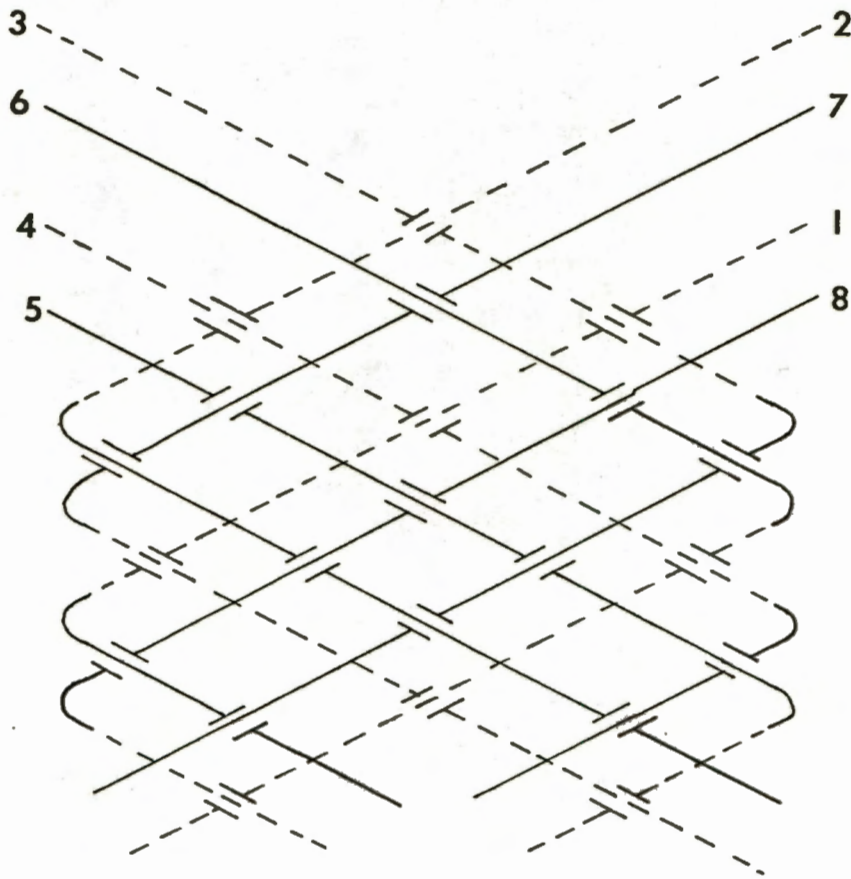
The electrode leads used were fashioned from bipolar pacemaker leads*. They consist of two conductive wires in the form of a space wound coil of nickel alloy encapsulated in silicone rubber. The unipolar resistance of each lead is about 1.29 ohms/cm.

The electrodes are constructed from 32 strand braided 0.0008" stress-relieved platinum wire** (92% Platinum; 8% Tungsten) and braided insulative spacing threads***. Each electrode consists of two parallel conducting wires woven in a helical fashion between the spacing threads as shown below. Threads 4 and 8 are the conducting wires. The weaving pattern is based on that of Timm & Bradley⁸² (1971) but has been modified to increase the strength of the weave so that each thread alternatively goes over and under its companions.

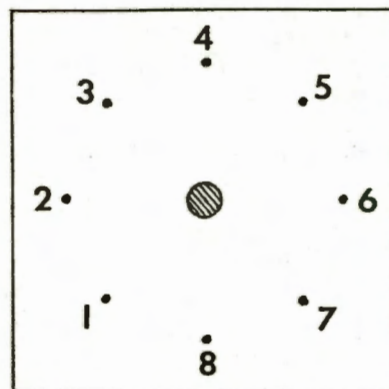
* MEDTRONIC INC., MINNESOTA, USA

** LEICO INDUSTRIES INC., NEW YORK, USA (SIGMUND COHN Alloy #479)

*** DEKNATEL INC., NEW YORK, USA (TEVDEK 5-0 green braided Teflon-impregnated Polyester Fibre. Code No.79-764)



Weaving is done by placing an upright wire on a board with a plastic tube fitted over the wire. The threads are stuck onto the board in the following manner as seen from above:



The threads are then woven according to the following table. The threads at the head of the table are placed under those in the table proper. The sequence starts at (a) until step (p) has been reached whereupon the whole process is repeated.

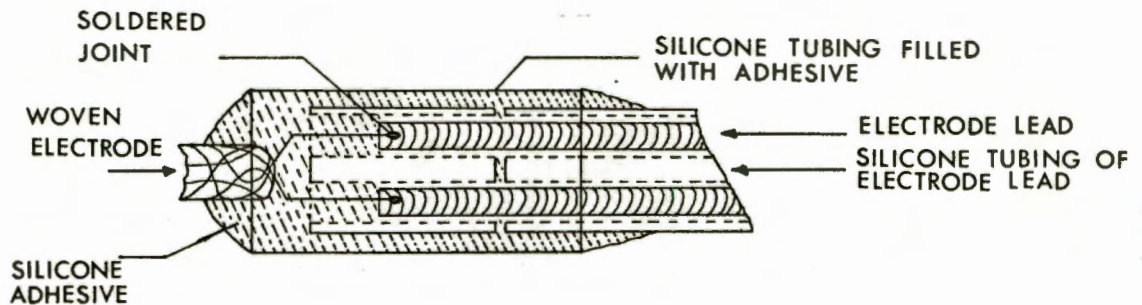
THREAD STEP	1	2	3	4	5	6	7	8
(a)		3						
(b)				2				
(c)			1					
(d)	4							
(e)						7		
(f)								6
(g)							5	
(h)					8			
(i)		7						
(j)						3		
(k)				6				
(l)							1	
(m)			5					
(n)								2
(o)					4			
(p)	8							

Electrode Specifications

Length:	5 cm
Diameter:	1.33 mm
Pitch:	1.33 mm

On completion of the winding, ends 3,4,5 and 6, and ends 1,2, 7 and 8 are tied together, the one end being passed through short bits of Silastic tubing* and glued with medical grade Silastic adhesive** as shown in Figure 9. Later this ending is also used to anchor the electrode in position on the bladder. The plastic tube is then slipped off the upright wire and the electrode is in turn slipped off the plastic tube.

The two conducting wires are passed through a short double silicone tube and soldered onto the ends of the electrode leads. The soldered ends are then pushed back into the silicone tube. The whole is filled with medical adhesive. A piece of Silastic tubing filled with medical adhesive is then placed around the joint thus sealing it completely as shown below:



The adhesive is also used to coat about 5 mm of the electrode since this is the entry point of the electrode into the bladder and it must be insulated to prevent current spread.

* DOW CORNING CORP., MICHIGAN, USA. (MEDICAL GRADE: I.D.=.04"; O.D.=.085")

** DOW CORNING CORP., MICHIGAN, USA. (SILICONE TYPE A, cat. No.890)

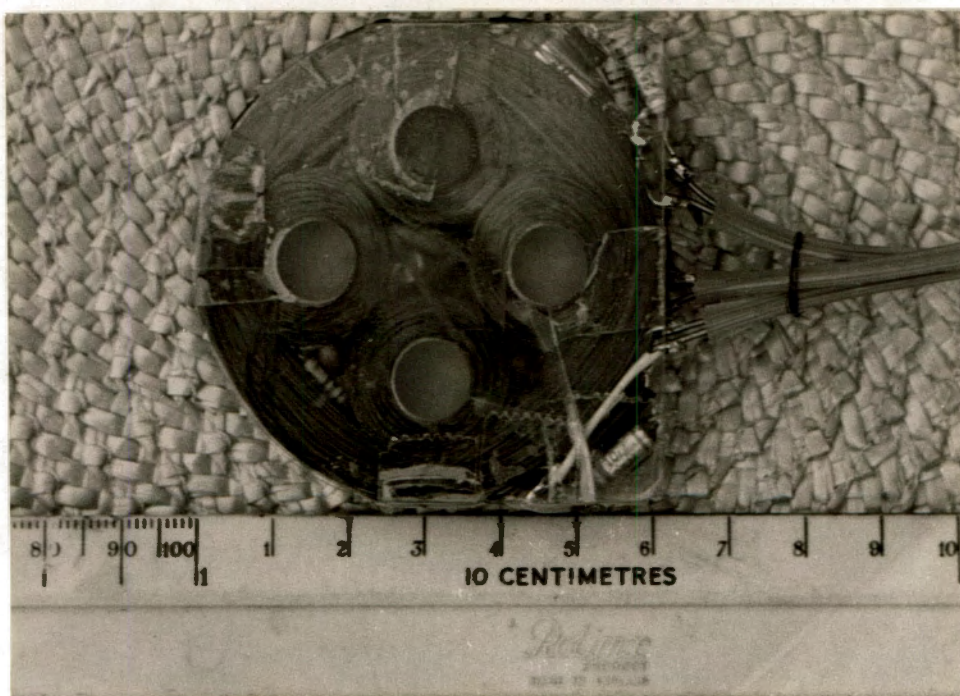


Fig. 8 RECEIVER PRIOR TO ENCAPSULATION SHOWING PLACEMENT OF ELECTRONIC COMPONENTS

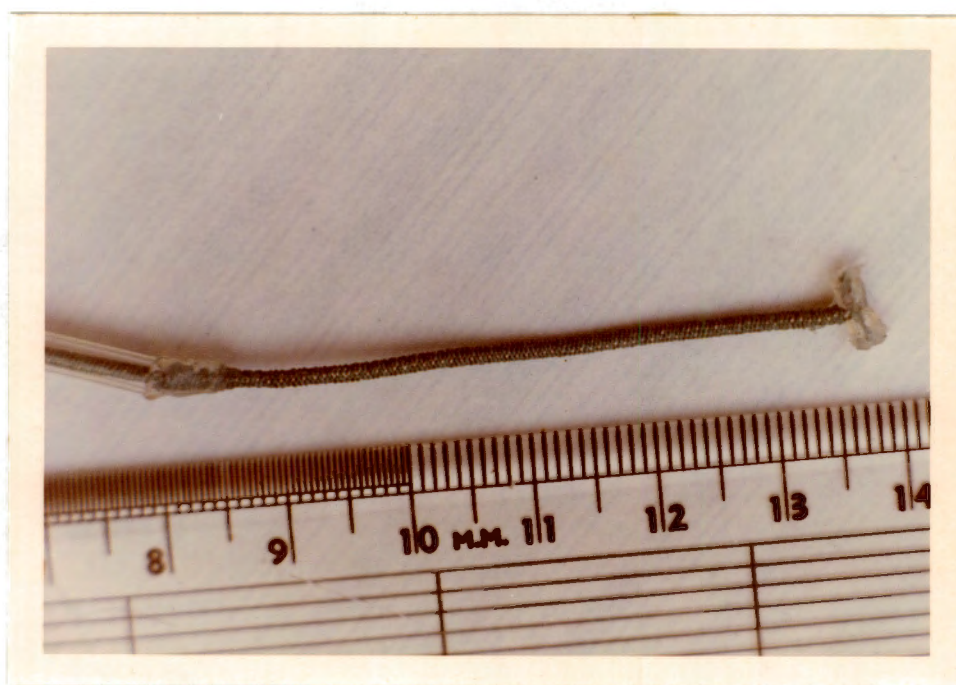


Fig. 9 WOVEN STIMULATING BIPOLAR ELECTRODE SHOWING ANCHOR AT END OF ELECTRODE AND THE TWO Pt WIRES APPEARING AS POINT ELECTRODES IN THE WEAVE

iii) Encapsulation

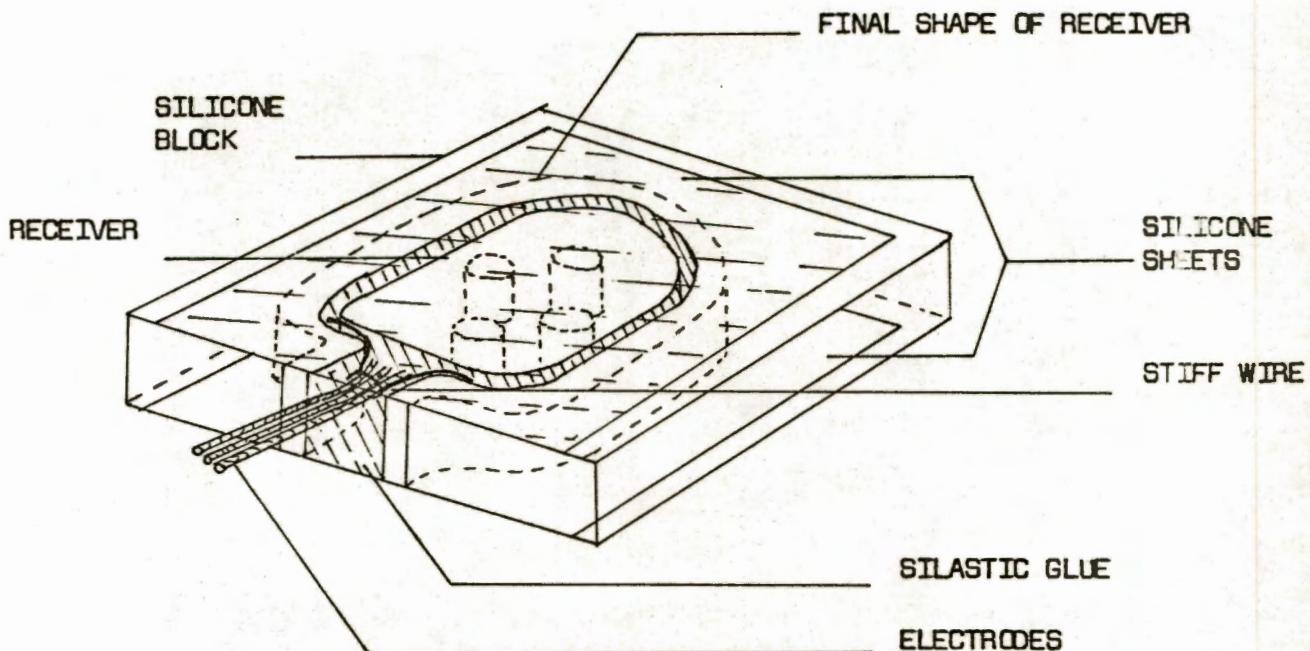
Because of the difficulty encountered in obtaining medical grade epoxy resins for incapsulation purposes in this country together with the availability of medical grade solid elastomers, it was decided to fashion a housing for the receiver in the following way:

a) A solid Silastic block* was carved so that the receiver fitted in it with the three electrode leads protruding through it.

b) A non-reinforced extra firm 0.04" thick Silastic sheet** was glued to the top and bottom of the block containing the receiver by means of the medical adhesive.

c) Using a scalpel, the whole was then fashioned to the required semi-circular shape after having cured for 24 hours.

To ensure that the electrode leads are firmly attached to the receiver, a stiff wire was wrapped about them, its ends splayed out so that the Silastic block absorbs any tugging on the leads.



* DOW CORNING CORP., MICHIGAN, USA (cat. No.803)

**

DOW CORNING CORP., MICHIGAN, USA (cat. No.502-1)

The encapsulated receiver can be seen in Figure 1.

The receiver was placed in a beaker of water and put in a vacuum chamber to ensure that no leaks occurred.

Prior to implantation, the receiver was washed with soap and rinsed under a tap, and then rinsed in distilled water. Finally it was gas sterilized and left for a week so that the ethylene oxide gas used could dissipate out.

The suitability of medical grade silicone elastomers for implant applications has been described by Lipshutz ⁵⁵ (1966). Of $12\frac{1}{2}\%$ of implants which had to be removed, only three were due to infection. This was due to improper cleaning prior to implantation. In all other cases no infection was found. This is confirmed by Jagannathan et al ⁵¹ (1969) who did a study of tissue reaction to silicone rubber. They found only minimal histologic evidence of such a reaction. Further references are given in the data sheets of the different silicone rubbers used ^{30, 31, 32}.

Specifications of receiver after encapsulation

Dimensions:	8x6.8x1.5 cms
Lead lengths:	22 cms
Electrode lengths:	5 cms
Total weight:	114 gms

9 FINAL TESTS ON THE STIMULATOR

9.1 LABORATORY TESTS

Prior to implantation the stimulator was tested in the laboratory to ensure correct functioning of the circuitry. Specifications are given below.

Specifications:

Pulse rate:

a) Per channel 20 pps

b) Overall 60 pps

Pulse duration: 1 ms

Output pulse amplitude at
1.2 cm separation between
transmitting and receiving
coils with 100 ohms load: 10 volts

Current drain from 9.6^V
batteries with 100 ohms
load and 1.2 cm separation: 0.7 amps

Dimensions of external
apparatus: 12.5x11x4.2 cms

Weight of external
apparatus:

a) With batteries 628.9 gms

b) Without batteries 433.5 gms

The change in mutual inductance for all three coils as the distance between transmitter and receiver is varied is shown in Figure 13. Included are calculated curves for comparison. Graphs showing variation of output voltage and power with load resistance appear in Figure 14.

Figure 10 shows the output voltage of the RF receiver across a 100 ohms load and Figure 11 illustrates the biphasic nature of the output waveform. The amount of pickup from the other two channels can be seen as two small white blips between each pair of pulses. The sequential pulsing of all three channels is illustrated in Figure 12.

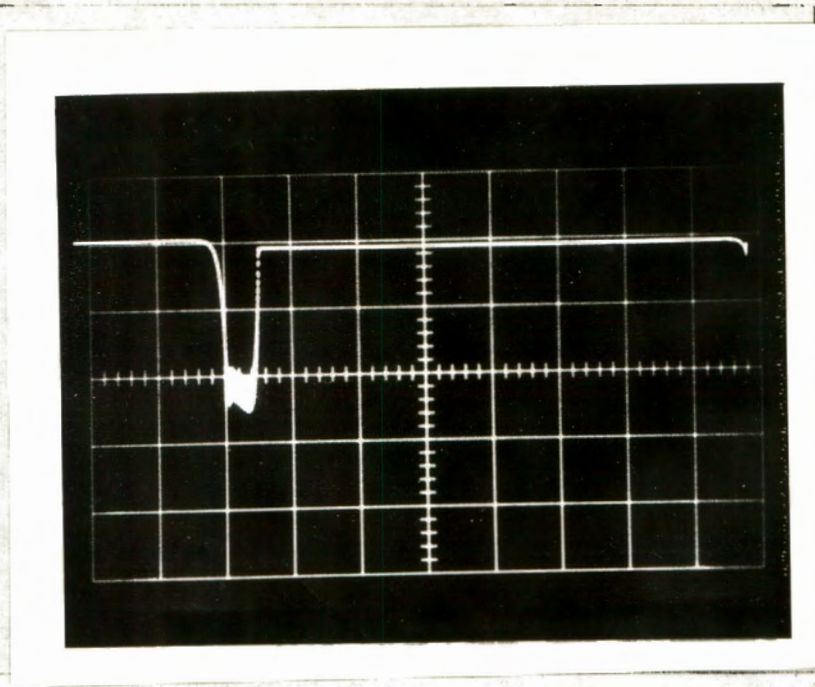


Fig. 10 OUTPUT VOLTAGE WAVEFORM FROM RECEIVER
VERTICAL: 1 div = 5 volts
HORIZONTAL: 1 div = 0.2 milliseconds

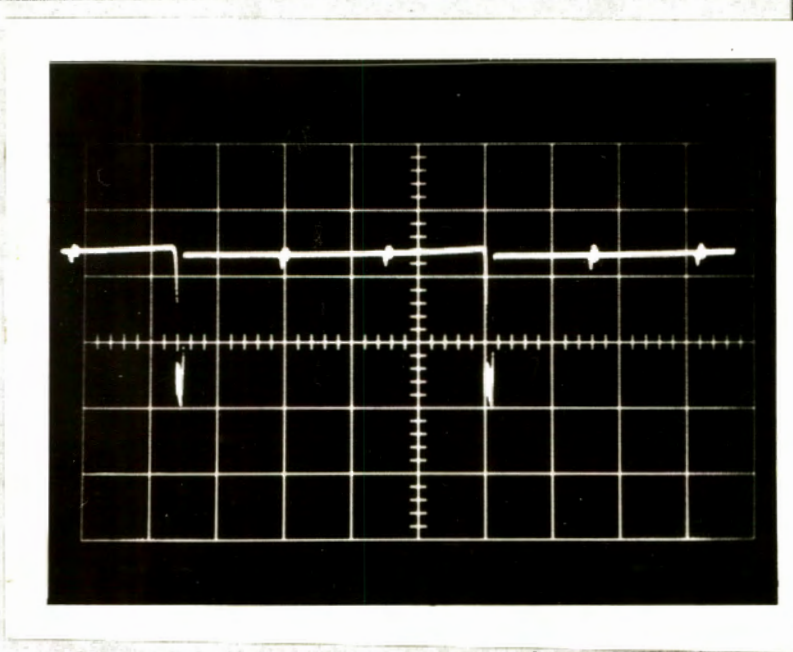


Fig. 11 OUTPUT FROM RECEIVER SHOWING BIPHASIC WAVEFORM
VERTICAL: 1 div = 5 volts
HORIZONTAL: 1 div = 10 milliseconds

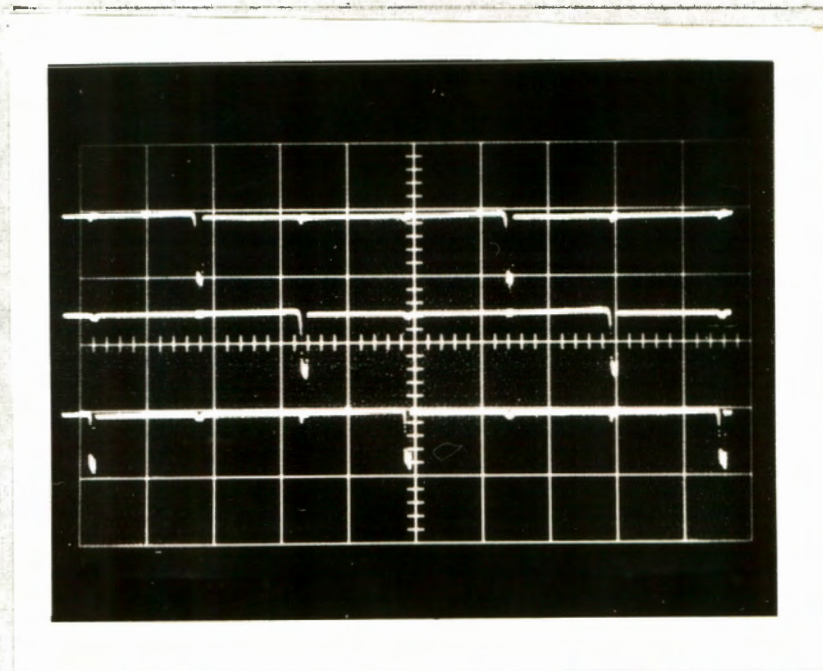


Fig. 12 OUTPUT VOLTAGE WAVEFORM FROM ALL THREE CHANNELS
SHOWING SEQUENTIAL PULSING
VERTICAL: 1 div = 10 volts
HORIZONTAL: 1 div = 10 milliseconds

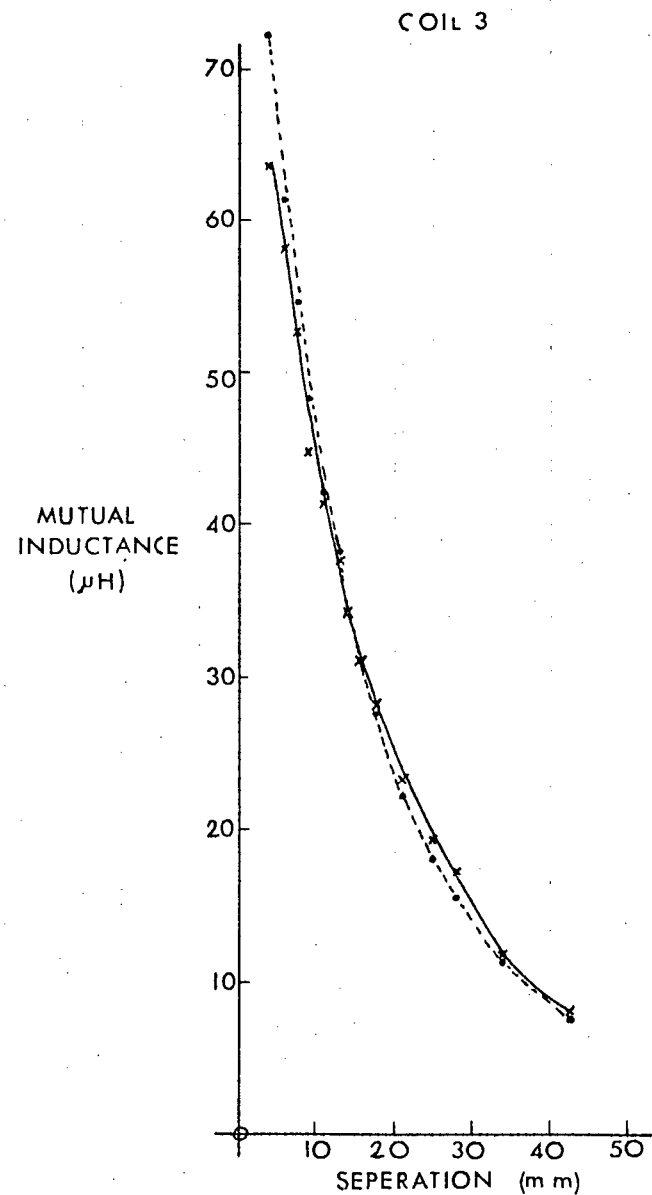
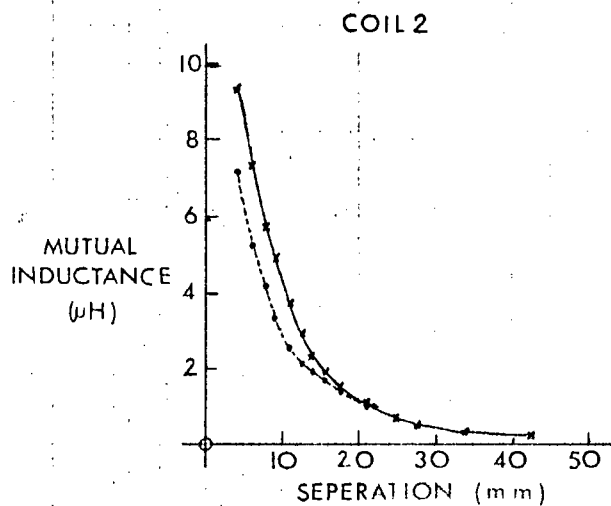
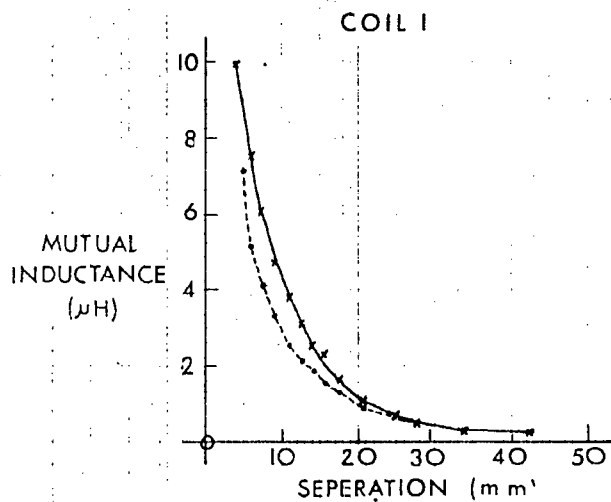


Fig. 13 GRAPH OF MUTUAL INDUCTANCE versus COIL SEPERATION

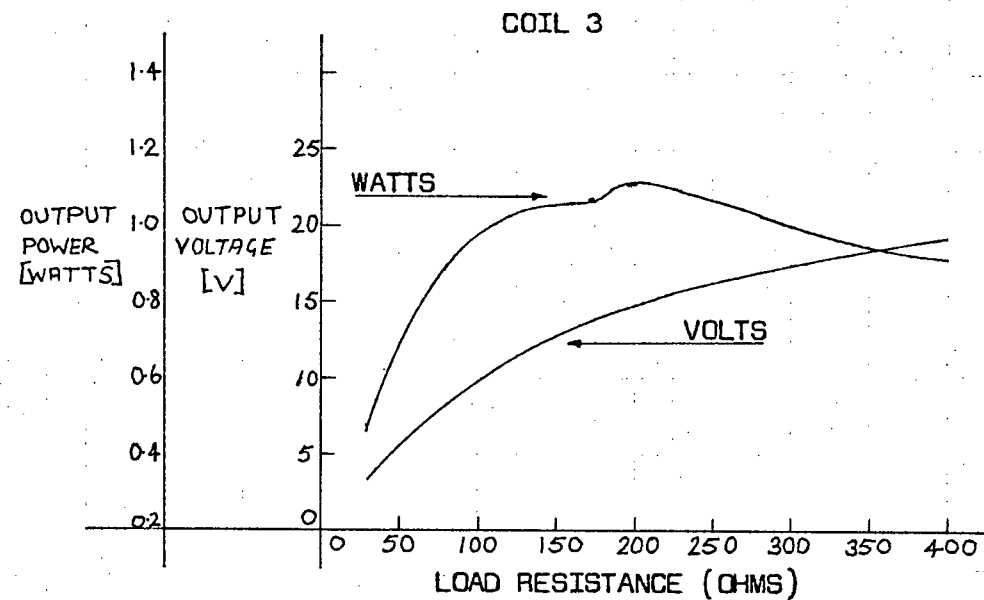
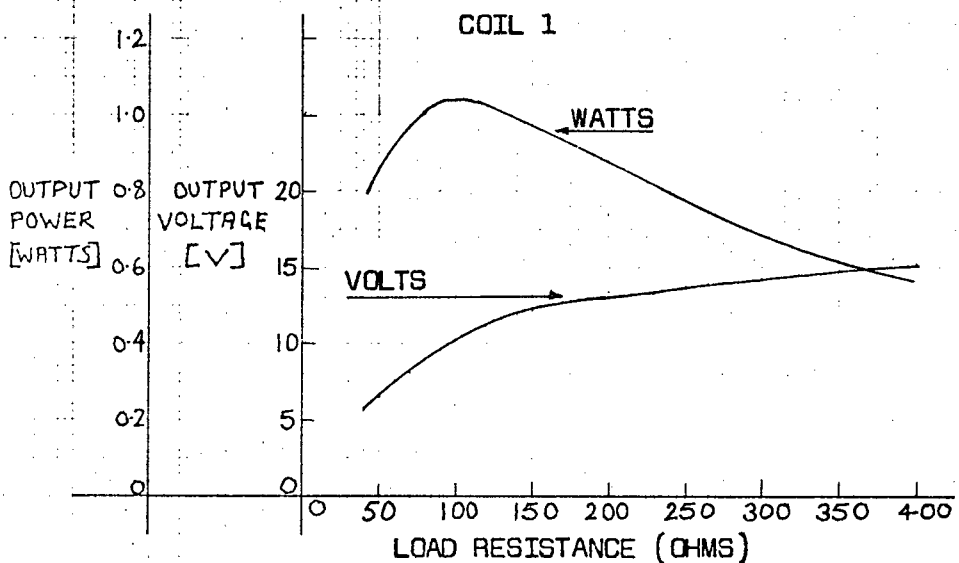
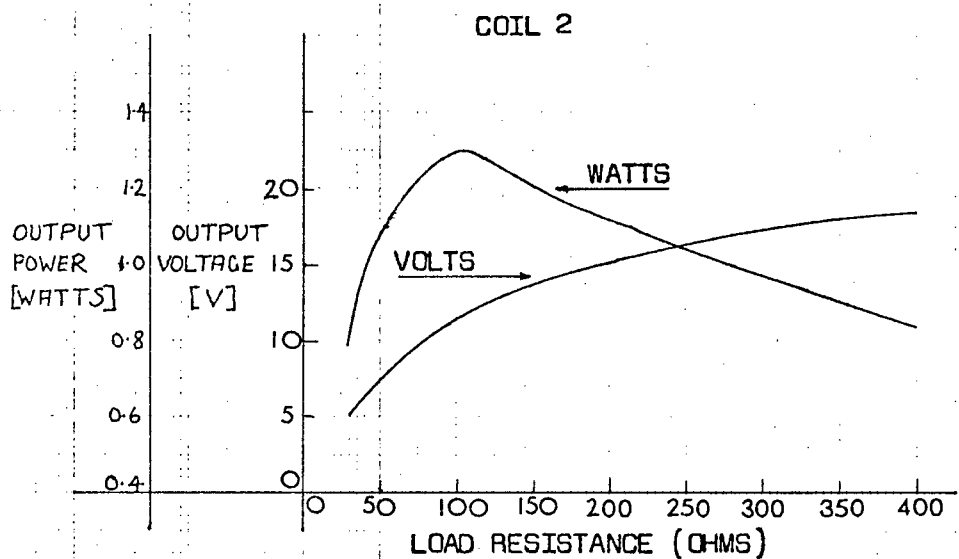


Fig. 14 GRAPH OF OUTPUT VOLTAGE AND OUTPUT POWER versus LOAD RESISTANCE

9.2. TRIAL OF THE STIMULATOR ON A PATIENT

i) Case History

The patient, a 22 year old tetraplegic (complete C4-5) was admitted on March 27, 1973 with no feeling below C5 as the result of a motorcar accident. In August of that year a CMG revealed a bladder capacity of 275-300 cc and one uninhibited contraction of 55 cms at a bladder volume of 50 cc. No sensation was present. Four days later bladder capacity had decreased. The patient could hardly void. In October, 1973, a CMG revealed uninhibited contractions at 150 and 175 cc of upto 17 and 39 cms respectively. The patient agreed to have the stimulator implanted. The operation to implant the stimulator was performed on November 5, 1973.

ii) Implantation Technique

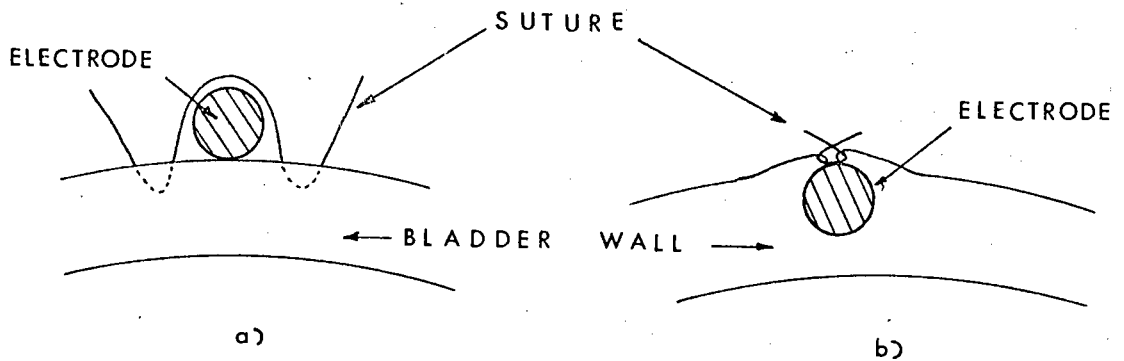
The following is quoted from the report in the patients personal file as described by the surgeon.

"Bladder exposed with transverse incision and filled via catheter to get better exposure and identification pelvic contents. Bladder exposed after dissection from surrounding fascia but it was extremely difficult as previous paracystitis had created adhesions ++.

"Peritoneal cavity inadvertently opened and also bladder due to attempt at separation of non-existent fascial planes. All peritoneal and bladder openings closed with purse string gut. Leads from control box x 3 buried in bladder wall posteriorly one and 2 laterally. Large $\frac{1}{2}$ " underwater drain put up."

The electrodes were positioned as suggested by Timm & Bradley⁸¹ (1969) i.e. two electrodes on the lateral ligaments on the ventral surface and the third one on the caudal-rostral midline of the dorsal surface.

The electrodes were imbricated into the wall of the bladder as follows:



Care was taken to ensure that no part of the electrodes would be exposed to neighbouring tissue thereby increasing current spread. The electrodes were too long and fascia was used to cover the protruding portions. The bladder was then isolated from surrounding tissue by means of Silastic sheeting*.

The electrode leads protruded through the skin, the receiver housing being located on the outside to restrict the extent of the incision. This also provided access to the electrode leads so that the stimulating levels could be measured. Postoperatively, the device was tested with no result.

iii) In Vivo Testing

The stimulator was tested one week postoperatively with little success. The patient was then X-rayed to ensure that the electrodes were still in position. The electrodes were then bared and an oscilloscope used to measure the stimulus voltage. With the bladder empty, the voltage measured across each electrode pair was in the order of 10^V . On filling the bladder with saline solution this voltage dropped to a few millivolts. It was then ascertained that the patient had a perforated bladder. At the time of the operation it was noted that the bladder wall was extremely thin in parts. An indwelling catheter was used to continuously drain the bladder. On December 12, 1973 a barium X-ray revealed that the hole had closed. No leakage was detected.

* DOW CORNING CORP., MICHIGAN, USA. (SILASTIC SHEETING REINFORCED, cat. No. 501-1)

This was subsequently confirmed when during stimulation the stimulus voltage dropped only to 8^V on filling the bladder with saline.

Testing recommenced on December 22, 1973. On stimulation, a pressure rise of only 3 cm H_2O was measured on a water barometer. At the same time the patient developed a reflex bladder which when contracting produced pressure rises in excess of 40 cm H_2O , sufficient to produce urination. On measuring the stimulus levels, the actual power input was found to be about 0.3 watts i.e. 8^V and 40 mA, about one third of the expected power input.

Because of recurrent infection of the patient and the failure of the device to produce sufficient intravesical pressure to effect voiding, the stimulator was removed on December 24, 1974.

9.3

READJUSTMENTS TO STIMULATOR

A possible explanation for the drop in output power is that the secondary circuits became detuned because of the presence of surrounding tissue. It was thus decided to increase the stimulus levels by replacing the power transistors with those of a higher rating and increasing the supply voltage.

The 80124 power transistors were replaced by SGS transistors (CPS 433) rated at 40 watts. The supply voltage was increased from 9.6^V to 15^V . The power developed across a 100 ohm resistor at a separation of 1.2 cm as shown in Figure 17 was 4 watts per channel. Submerging the electrodes in saline solution produced the following:

ELECTRODE PAIR	VOLTS	AMPS	WATTS
1	13	0.13	1.69
2	15	0.12	1.80
3	18	0.14	2.52

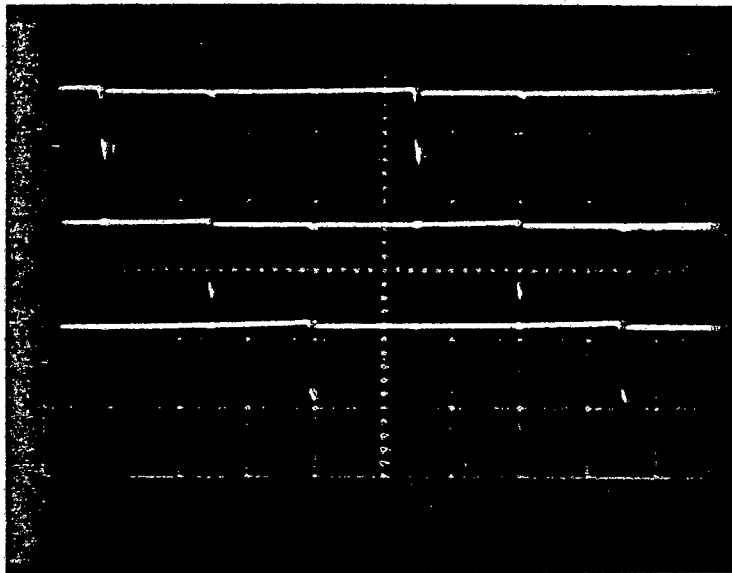


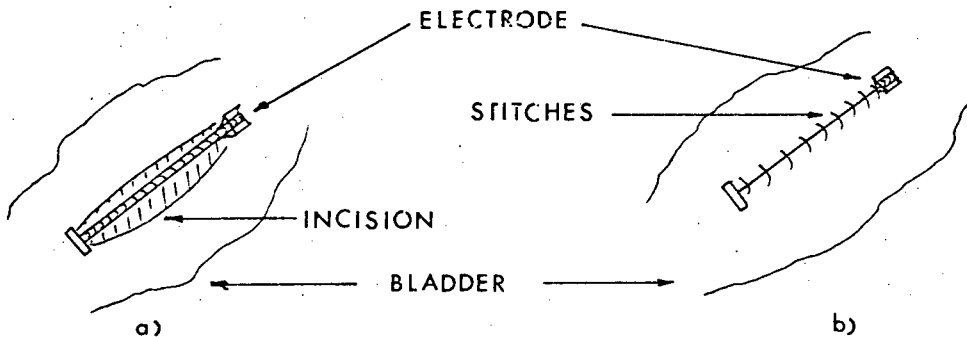
Fig. 17 OUTPUT VOLTAGE WAVEFORMS ACROSS 100 ohm
LOAD AFTER READJUSTMENTS
VERTICAL: 1 div = 20 volts
HORIZONTAL: 1 div = 10 milliseconds

9.4

TRIAL OF STIMULATOR IN AN ANIMAL

The stimulator was reimplanted in a sow on January 22, 1974. The only differences in operating procedure were:

a) Instead of imbricating the electrodes as had been done in the case of the patient, cuts were made into the bladder wall and the electrodes placed in these and then stitched in position as shown:



This ensured closer contact between the electrodes and the bladder musculature.

b) Because the peritoneum is so thin and delicate in the pig, the insulating Silastic sheeting was placed over the peritoneum whereas before it was placed on the wall itself. Tissue reaction to the Silastic sheeting had been observed when the stimulator was removed from the patient. Thus only short strips were sutured over the electrodes embedded in the detrusor.

c) The internal unit was completely implanted, the receiver being placed under the skin. The electrode leads had been shortened to an overall length of 16 cm.

Stimulation was attempted whilst the bladder was exposed with no result. On opening the external unit, a loose connection was found. This was repaired and on completion of the operation stimulation was again attempted. The sow voided well whilst still under anaesthetic. The urinary stream was not continuous but flowed in short bursts accompanied with twitching of the anus as is usual in such species. There were no signs of current

spread whatsoever i.e. twitching of the limbs or contraction of the pelvic floor and abdominal muscles. The stimulator was next tested two days later. The sow again voided well except that twitching of the tail was noted. The stimulation was performed with the sow awake. There was no evidence of pain.

In order to evaluate the performance of the stimulator, intravesical pressure and initial and residual urine volumes had to be measured. Attempts to introduce a catheter into the bladder via the urethra succeeded after a week but whilst transporting the sow to the operating theatre, the catheter became dislodged. No further attempts were made to catheterise the sow as she had opened the stitches by vigorously rubbing her abdomen against a concrete floor. Infection had set in and the experiment had to be terminated.

10 CONCLUSIONS10.1 ANALYSIS OF CLINICAL TRIALS

The response of the bladder to electrical stimulation is a function of the state of tonus of the detrusor, bladder capacity, area of muscle stimulated, and stimulus intensity. The failure of the stimulator to evoke sufficient contraction of the bladder to effect voiding when tested in the patient was first thought to be solely due to atrophy of the detrusor muscle. It was noted during the operation to implant the stimulator that flaps of dead detrusor muscle hung from the bladder. The subsequent development by the patient of a reflex bladder which produced intravesical pressures in excess of 70 cm H₂O, demonstrated that the detrusor muscle had sufficient tonus to produce contraction and evacuation.

Minimum pulse amplitudes used by previous investigators which produced voiding are listed below:

6 ^v	(Ellis et al ³³ , 1965)
6 ^v	(Susset & Boctor ⁷³ , 1967)
2-5 ^v	(Wear et al ⁸⁴ , 1967)
8 ^v	(Shabazian ⁶⁷ , 1969)

A reflex bladder is extremely sensitive to any irritation. The failure of the stimulator to evoke more than a 3 cm H₂O rise in intravesical pressure using measured pulse amplitudes of 8^v thus indicates that:

- a) the bladder musculature was impaired to some degree.
- b) the type of electrode used, because it restricts current spread, may require increased activation in order to excite the same muscle volume as disc, plate or wire electrodes.

Besides the increase in stimulating levels, a further factor which may have enhanced the effectiveness of the stimulator when implanted in the sow is the method used to insert the electrodes

into the bladder wall. Further experiments are needed to evaluate the difference between imbrocating the electrodes and stitching them into incisions in the muscle wall.

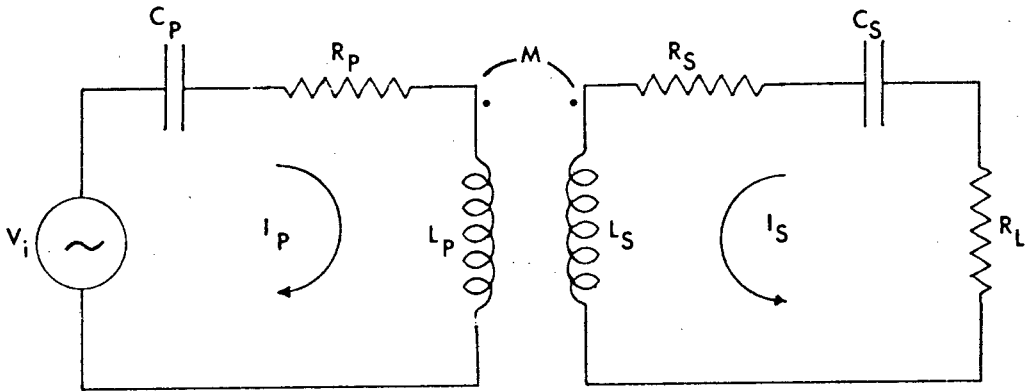
Whilst the stimulator induced voiding in the sow with no visible current spread or pain, it was impossible to evaluate the device any further as the sow had to be destroyed. Also, the bladder of the sow was not denervated so that the stimulator requires further testing on different types of neurogenic bladder. Extensive clinical trials of the stimulator of several months duration are thus required to establish the device as a reliable method for the treatment of urinary retention.

10.2 FUTURE POSSIBILITIES

The aim of electrostimulation of the urinary bladder is to mimick the natural order of micturition. To duplicate the contractile sequence found during reflex induction in the normal bladder, it may be necessary to deliver variable pulse sequences and combinations to the bladder (Timm & Bradley⁸³, 1973). The system developed by the author to transmit three independent signals through the intact skin lends itself to this application.

APPENDIX A: EFFICIENCY OF TRANSPORT OF ENERGY BETWEEN TWO COILS

Consider the following circuit:



At resonance:

Voltage equation around primary loop is:

$$v_i = I_P R_P + j\omega M I_S \quad \text{-----} \quad (I)$$

Voltage equation around secondary loop is:

$$0 = I_P j\omega M + I_S (R_S + R_L)$$

$$\therefore I_S = - \frac{j\omega M}{R_S + R_L} I_P \quad \text{and substitute in (I)}$$

$$\therefore v_i = I_P \left[R_P + \frac{\omega^2 M^2}{R_S + R_L} \right]$$

Input power

$$P_i = v_i I_P$$

$$= |I_P|^2 \left[R_P + \frac{\omega^2 M^2}{R_S + R_L} \right]$$

Output power

$$P_o = |I_s|^2 R_L$$

$$= \frac{w_M^2 I_p^2}{(R_S + R_L)^2} R_L$$

Efficiency

$$\eta = P_o / P_i$$

$$= \frac{w_M^2 R_L}{(R_S + R_L)^2} \left[\frac{R_S + R_L}{w_M^2 + R_P(R_S + R_L)} \right]$$

$$= \frac{R_L}{R_S + R_L} \left[\frac{1}{1 + \frac{R_P(R_S + R_L)}{w_M^2}} \right] \quad \text{---} \quad (I_A)$$

APPENDIX B: OPTIMUM LOAD

In the expression for efficiency derived in Appendix A, for a given set of coils, frequency and spacing, the only variable is the series load resistor, R_L . Thus differentiating the expression for efficiency with respect to R_L and equating the result to zero should yield the value of R_L at which maximum efficiency occurs.

$$\eta = \frac{R_L}{R_S + R_L} \left[\frac{1}{1 + \frac{R_P(R_S + R_L)}{w_M^2}} \right]$$

$$\begin{aligned}
\frac{\partial \mathcal{A}}{\partial R_L} &= \left[\frac{1}{1 + \frac{R_P(R_S + R_L)}{w_M^2}} \right] \left[\frac{R_S + R_L - R_L}{(R_S + R_L)^2} \right] \\
&\quad + \left[\frac{R_L}{R_S + R_L} \right] \left[\frac{-R_P / w_M^2}{\left\{ 1 + \frac{R_P(R_S + R_L)}{w_M^2} \right\}^2} \right] \\
&= \left[\frac{1}{1 + \frac{R_P(R_S + R_L)}{w_M^2}} \right] \left[\frac{R_S}{(R_S + R_L)^2} - \frac{R_L}{(R_S + R_L)} \frac{R_P}{\{w_M^2 + R_P(R_S + R_L)\}} \right] \\
&= \left[\frac{1}{1 + \frac{R_P(R_S + R_L)}{w_M^2}} \right] \left[\frac{1}{R_S + R_L} \right] \left[\frac{w_M^2 R_S + R_P R_S^2 - R_L^2 R_P}{(R_S + R_L) \{w_M^2 + R_P(R_S + R_L)\}} \right] \\
&= 0 \quad \text{for a maximum.}
\end{aligned}$$

$$\therefore w_M^2 R_S + R_P R_S^2 - R_L^2 R_P = 0$$

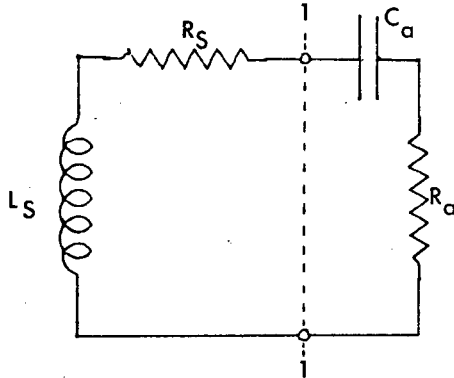
$$R_L = \sqrt{\frac{w_M^2 R_S}{R_P} + R_S^2} \quad \text{_____} \quad (I_B)$$

For identical coils, $R_S = R_P$

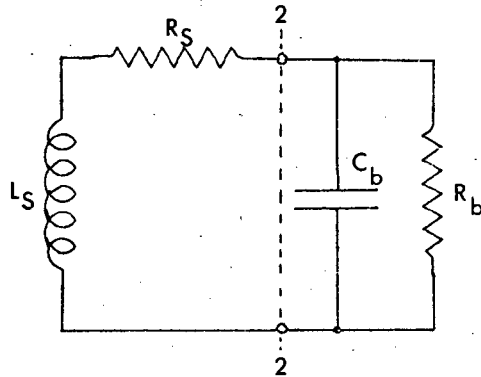
$$\therefore R_L = \sqrt{w_M^2 + R_S^2} \quad \text{_____} \quad (II_B)$$

APPENDIX C: EQUIVALENT SERIES AND PARALLEL RESISTANCES AND CAPACITANCES

Consider the following two circuits;



$$Z_1 = R_a + \frac{1}{j\omega C_a} \quad ;$$



$$Z_2 = \frac{R_b}{1 + j\omega C_b R_b}$$

$$= \frac{R_b(1 - j\omega C_b R_b)}{1 + \omega^2 C_b^2 R_b^2}$$

For $Z_1 = Z_2$

Reals:

$$R_a = \frac{R_b}{1 + \omega^2 C_b^2 R_b^2} \quad \text{-----} \quad (I_C)$$

Imaginary:

$$\frac{1}{j\omega C_a} = \frac{-j\omega C_b R_b^2}{1 + \omega^2 C_b^2 R_b^2}$$

$$\therefore C_a = \frac{1 + \omega^2 C_b^2 R_b^2}{\omega^2 C_b R_b^2} = C_b + \frac{1}{\omega^2 C_b R_b^2} \quad \text{-----} \quad (II_C)$$

$$= C_b \left[1 + \frac{1}{\omega^2 C_b^2 R_b^2} \right]$$

From (I_C) : $R_a + \omega^2 C_b^2 R_b^2 R_a = R_b$

$$\therefore C_b^2 = \frac{R_b - R_a}{w^2 R_b^2 R_a}$$

$$C_b = \frac{\sqrt{R_b / R_a - 1}}{w R_b} \quad \text{-----} \quad (III_C)$$

and substitute in (II_C)

$$\begin{aligned} C_a &= \frac{\sqrt{R_b / R_a - 1}}{w R_b} + \frac{w R_b}{w^2 R_b^2 \sqrt{R_b / R_a - 1}} \\ &= \frac{R_b / R_a - 1 + 1}{w R_b \sqrt{R_b / R_a - 1}} \\ &= \frac{1}{w R_a \sqrt{R_b / R_a - 1}} \end{aligned}$$

$$\therefore C_a^2 = \frac{1}{w^2 R_a^2 (R_b / R_a - 1)}$$

$$w^2 C_a^2 R_a R_b - w^2 C_a^2 R_a^2 = 1$$

$$R_b = R_a \left[1 + \frac{1}{w^2 C_a^2 R_a^2} \right] \quad \text{-----} \quad (IV_C)$$

and substitute in (III_C)

$$C_b = \frac{\sqrt{1 + \frac{1}{w^2 C_a^2 R_a^2} - 1}}{w R_a \left(1 + \frac{1}{w^2 C_a^2 R_a^2} \right)}$$

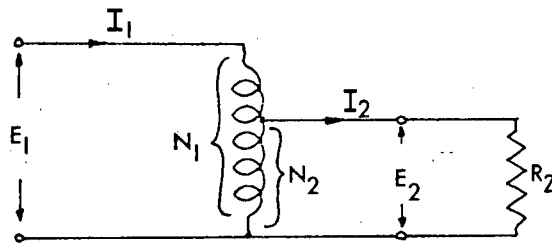
$$\therefore C_b = \frac{C_a}{1 + w^2 C_a^2 R_a^2} \quad \text{---} \quad (V_C)$$

Thus equations (I_C) and (II_C) provide for the transformation from a parallel to a series load, and equations (IV_C) and (V_C) for that of a series to a parallel load.

APPENDIX D: IMPEDANCE MATCHING

Having calculated the optimum series load from Appendix B and having converted it to the equivalent parallel load from Appendix C, it must now be matched to the actual load. The principle of the auto-transformer lends itself to this since all that is required is an appropriate tapping on the secondary coil, and no additional components.

Consider the following circuit:



From the theory of transformers, it follows that:

$$\frac{N_1}{N_2} = \frac{E_1}{E_2} = \frac{I_2}{I_1} \quad \text{---} \quad (I_D)$$

where N_1 = total number of turns on coil.
 N_2 = number of turns of tapping.

$$\therefore \left(\frac{N_1}{N_2} \right)^2 = \frac{E_1}{E_2} \cdot \frac{I_2}{I_1}$$

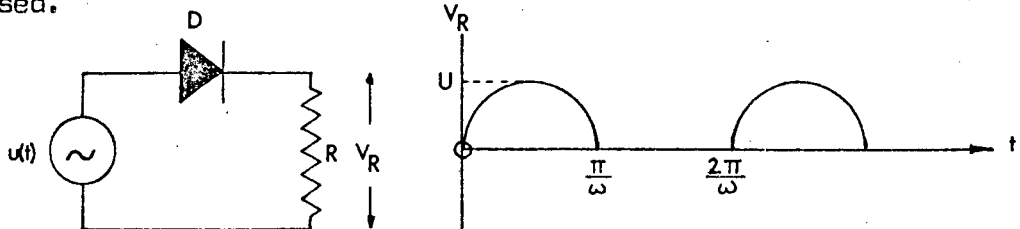
$$= \frac{R_1}{R_2} \quad \text{---} \quad (II_D)$$

where R_1 = resistance as calculated from equation (IV_C)

R_2 = resistance of bladder circuit.

APPENDIX E: CONVERSION OF AC TO DC POWER

Consider the case where only a diode with no smoothing capacitor is used.



Using Fourier, since $u(t) = U \sin(\omega t)$

$$v_R(t) = U \sin(\omega t) \quad 0 \leq t \leq \pi/\omega$$

$$= 0 \quad \pi/\omega \leq t \leq 2\pi/\omega$$

$$2e_{DC} = \frac{\omega}{\pi} \int_0^{\pi/\omega} U \sin(\omega t) dt$$

$$= \frac{\omega}{\pi} \left(\frac{2U}{\omega} \right)$$

$$\therefore e_{DC} = \frac{U}{\pi}$$

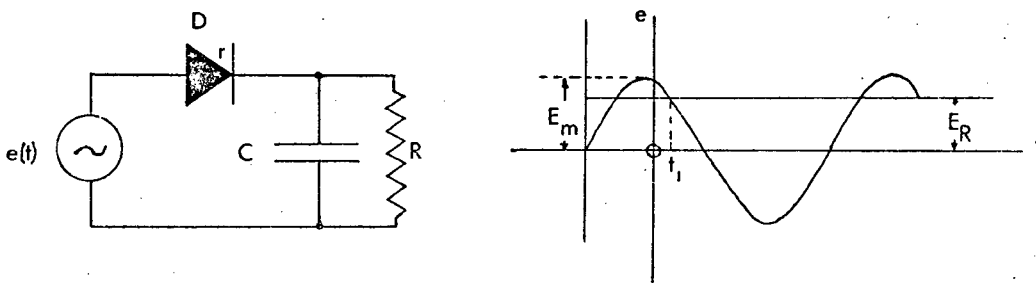
$$P_{DC} = \frac{U^2}{\pi^2 R}$$

Similarly, if the diode were not in circuit it can be shown that:

$$P_{rms} = \frac{U^2}{2R}$$

and since it is the DC power that produces the stimulus, a more efficient method is needed to convert the AC power to DC.

Consider now the case where a capacitor is inserted into the above circuit as shown:



Applied voltage = $E_m \cos(\omega t)$

Assume that E_r = mean voltage across load

e_p = voltage across rectifier

then $e_p = E_m \cos(\omega t) - E_r$

Current through rectifier

$$i_p = \frac{E_m \cos(\omega t) - E_r}{r} \quad e_p > 0$$

$$= 0 \quad e_p < 0$$

Change occurs at angle ωt_1 so that

$$\cos(\omega t_1) = \frac{E_r}{E_m} \quad \text{—————} \quad (I_E)$$

Quantity of electricity (charge) passed is the same through the rectifier as through the resistance.

Quantity passed through resistance in one cycle

$$\begin{aligned} &= \frac{I_R}{T} = \frac{2\pi I_R}{\omega} = \frac{2\pi E_r}{\omega R} \\ &= \frac{2\pi E_m \cos(\omega t_1)}{\omega R} \quad \text{from } (I_E) \end{aligned}$$

Quantity passed through rectifier in one cycle

$$\begin{aligned} &= 2 \int_0^{t_1} \frac{E_m \cos(\omega t) - E_r}{r} dt \\ &= 2 \int_0^{t_1} \frac{E_m \cos(\omega t) - E_m \cos(\omega t_1)}{r} dt \quad \text{from } (I_E) \\ &= \frac{2E_m}{\omega r} (\sin(\omega t_1) - \omega t_1 \cos(\omega t_1)) \end{aligned}$$

Since these two quantities are equal

$$\frac{2E_m}{\omega r} (\sin(\omega t_1) - \omega t_1 \cos(\omega t_1)) = \frac{2\pi E_m \cos(\omega t_1)}{\omega R}$$

$$\frac{\pi r}{R} = \frac{\sin(wt_1) - wt_1 \cos(wt_1)}{\cos(wt_1)}$$

$$\frac{R}{r} = \frac{\pi}{\tan(wt_1) - wt_1} \quad \text{-----} \quad (II_E)$$

where

r = resistance of diode + source resistance when diode is conducting.

Instantaneous voltage $e = E_m \cos(wt)$

Instantaneous current $i = \frac{E_m \cos(wt) - E_R}{r}$

Instantaneous power $= \frac{E_m^2 \cos^2(wt) - E_m E_R \cos(wt)}{r}$

Energy supplied in one cycle

$$= \frac{1}{r} \int_0^{wt_1} (E_m^2 \cos^2(wt) - E_m E_R \cos(wt)) d(wt)$$

$$= \frac{E_m}{r} \left[\frac{E_m}{2} wt_1 + \frac{E_m}{4} \sin(2wt_1) - E_R \sin(wt_1) \right]$$

$$= \frac{E_m^2}{r} \left[\frac{wt_1}{2} + \frac{\sin(wt_1) \cos(wt_1)}{2} - \sin(wt_1) \cos(wt_1) \right]$$

from (I_E)

$$= \frac{E_m^2}{r} \left[\frac{wt_1}{2} - \frac{\sin(wt_1) \cos(wt_1)}{2} \right]$$

If the time constant of the shunt capacitor and resistor is large compared with one period, then the current with the capacitor is π times the current without the capacitor.

If R_{eq} = the equivalent load the source 'sees' with the capacitor in circuit, then

Energy supplied in 1 cycle to R_{eq}

$$= \frac{\pi E_m^2}{2R_{eq}} = \frac{E_m^2}{2r} \left[wt_1 - \sin(wt_1)\cos(wt_1) \right]$$

$$\text{Also } r = \frac{R(\tan(wt_1) - wt_1)}{\pi} \quad \text{from (II}_E\text{)}$$

$$\therefore \frac{R_{eq}}{R} = \frac{\tan(wt_1) - wt_1}{wt_1 - \sin(wt_1)\cos(wt_1)} \quad \text{--- (III}_E\text{)}$$

APPENDIX F: CALCULATIONS

Initially the primary and secondary coils constructed had the same dimensions, number of strands and turns, and wire gauge. These coils were used to compare the theory developed for predicting the performance of coils with measured results. The primary coils were then reconstructed to enable the use of a practical value of supply voltage. Appropriate tapings were taken to match load and source impedances.

F1: THE TEST COILS

a) Inductance and RF Resistance

Using Reyners formula for inductance (see Section 7.2(i)) where

$$D = 1.9 \text{ cm} = 0.748''$$

$$d = .45 \text{ cm} = 0.173''$$

$$l = .6 \text{ cm} = 0.2361''$$

$$N = 130 \text{ turns per coil-side.}$$

$$\begin{aligned}
 L &= \frac{0.2N^2D^2}{3.5D + 61} \times \frac{D - 2.25d}{D} \mu H \\
 &= \frac{0.2 \times 16900 \times 0.748(0.748 - .3895)}{2.62 + 1.891} \\
 &= \frac{3380 \times .748 \times .3585}{4.511} \\
 &= 0.2006 \text{ mH}
 \end{aligned}$$

Since there are two coil-sides per coil, the total inductance

$$L_T = 0.4012 \text{ mH}$$

Length of wire used, $\mathcal{L} = \pi D_m N$ yds.

where D_m = mean diameter of coil in yards.

DC Resistance

$$R_{DC} = \frac{\mathcal{L}r}{n}$$

where r = resistance of strand in ohms/yd

n = number of strands

$$D_m = 0.57''; \quad r = 1.33 \text{ ohms/yd}; \quad n = 7 \text{ strands}$$

$$\therefore R_{DC} = \frac{\pi \times 0.57 \times 260 \times 1.33}{36 \times 7}$$

$$= 2.46 \text{ ohms using SWG 40 wire.}$$

Using a chart for calculating the ratio of RF to DC resistance of a coil⁶, it is possible to calculate the skin factor and proximity factor of a coil at a certain frequency. Since the ratio of RF resistance to DC resistance is equal to the sum of the skin and proximity factors, the RF resistance of the coil at the frequency of operation can be found.

From the curves, S.F. = 1; P.F. = 1.98

$$\begin{aligned}
 \therefore R_{RF} &= R_{DC}(S.F. + P.F.) \\
 &= 2.46(1 + 1.98) \\
 &= 7.33 \text{ ohms} \quad \text{at } 190 \text{ KHz}
 \end{aligned}$$

b) Coefficient of coupling and mutual inductance.

Using the formula derived by Amos (see Section 7.2(i)) for the coupling coefficient where

$$a = l = 0.2361"; \quad b = 0.2361 + .472 = 0.7081"$$

$$\text{where the distance between coils is} \quad c = 1.2 \text{ cm} = .472"$$

$$e = b + a = 0.9442"; \quad D = 0.748"$$

$$\begin{aligned}
 K &= \frac{\left(1 + \frac{2.3a}{D}\right)}{\left(1 + \frac{2.3b}{D}\right) \left(1 + \frac{2.3c}{D}\right) \left(1 + \frac{2.3e}{D}\right)} \\
 &= \frac{\left(1 + \frac{2.3 \times .2361}{.748}\right)}{\left(1 + \frac{2.3 \times .7081}{.748}\right) \left(1 + \frac{2.3 \times .472}{.748}\right) \left(1 + \frac{2.3 \times .9442}{.748}\right)} \\
 &= \frac{1.726}{3.18 \times 2.45 \times 3.9} \\
 &= 0.0567
 \end{aligned}$$

Mutual inductance

$$\begin{aligned}
 M &= K \sqrt{L_P L_S} \\
 &= KL \\
 &= 0.0567 \times 0.4012 \times 10^{-3} \\
 &= 22.8 \mu\text{H}
 \end{aligned}$$

Frequency $f = 190 \text{ KHz}$

$$\therefore Q = \frac{2\pi 1.9 \times 10^5 \times 4.012 \times 10^{-4}}{7.33} = 65.4$$

where Q = unloaded Q -factor of the primary and secondary coils.

c) Optimum series load resistance.

From Appendix B, equation (II_B)

$$\begin{aligned} R_L &= \sqrt{w^2 M^2 + R_S^2} \\ &= \sqrt{1.422 \times 520 + 53.7} \\ &= \sqrt{740 + 53.7} \\ &= 28.17 \text{ ohms.} \end{aligned}$$

d) Efficiency of transport of energy.

From Appendix A, equation (I_A) where

$$R_L = 28.17 \text{ ohms}$$

$$R_S = 7.33 \text{ ohms}$$

$$R_P = 7.33 \text{ ohms}$$

$$M = 22.8 \text{ } \mu\text{H}$$

$$f = 190 \text{ KHz}$$

Efficiency

$$\begin{aligned} \eta &= \frac{28.17}{(28.17 + 7.33)} \left[\frac{1}{1 + \frac{7.33(28.17 + 7.33)}{1.422 \times 520}} \right] \\ &= 0.792 \left[\frac{1}{1 + .3518} \right] \\ &= 0.585 \end{aligned}$$

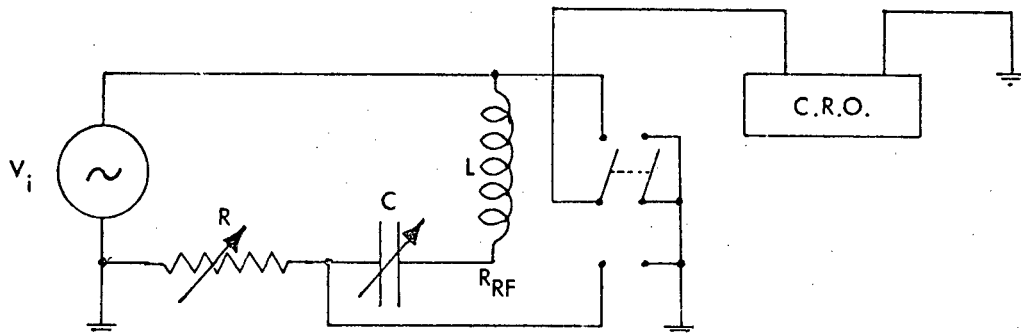
$$\text{i.e. } \% \eta = 58.5 \%$$

e) Comparison of theoretical and measured values.

Inductance and DC resistance were measured on a G.R. impedance bridge*.

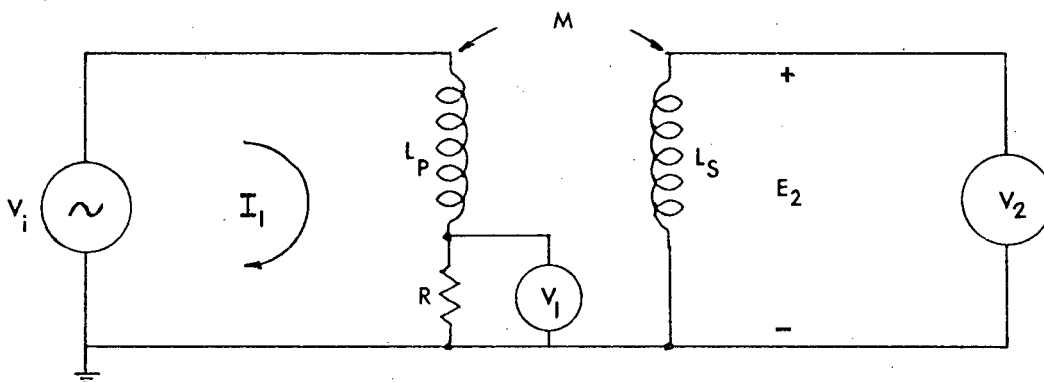
*General Radio Impedance Bridge (Type 1650-A)

Measurement of RF resistance:



Coil L is tuned by capacitor C to resonate at the required frequency. Voltage across the resonant circuit and current through it are measured, the latter by using a small series resistor R . Keeping the input voltage constant, resistor R is increased until the circulating current is one half of its former value. The above is based on the maximum power transfer theorem, the source resistance R being equal to the load resistance, R_{RF} .

Measurement of mutual inductance, M :

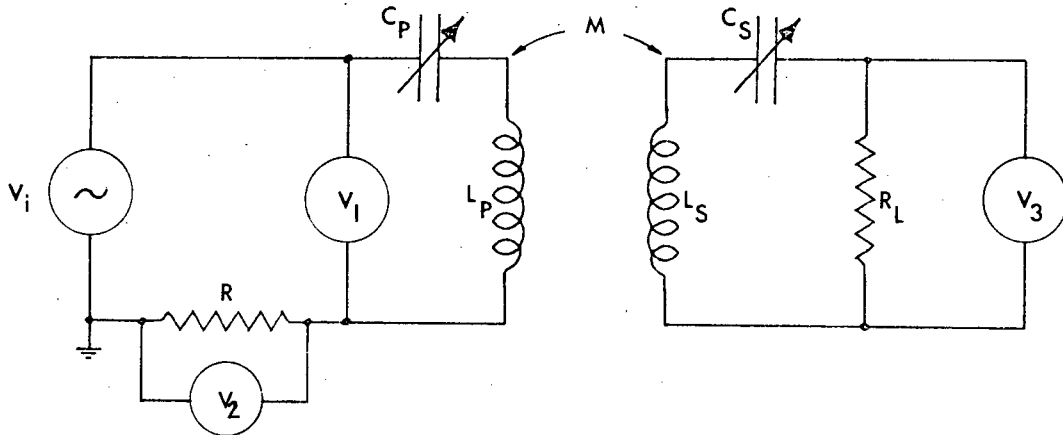


When the secondary coil is open circuited, the following relationship holds:

$$E_2 = -j\omega M I_1$$

The primary current I_1 is measured via resistance R , and the secondary voltage via a high impedance measuring device (C.R.O.).

Measurement of efficiency:



Both primary and secondary circuits are series tuned at the required frequency. Primary voltage and current are noted together with load voltage. Because they are tuned, both circuits are purely resistive so that output current can be calculated and hence the efficiency of power transfer.

The optimum series load was found experimentally by measuring the efficiency for different values of load resistance.

The results of the above measurements together with theoretical values are listed below:

MEASURED	L (mH)	R _{DC} (ohms)	R _{RF} (ohms)	M (μH)	R _L (ohms)	% <i>η</i>
PRIMARY	.403	2.54	7.81	23.38	30	53.9
SECONDARY	.412	2.6	8			
THEORETICAL						
PRIMARY	.4012	2.46	7.33	22.8	28.17	58.5
SECONDARY	.4012	2.46	7.33			

The good correlation between theoretical and practical results thus enables the theory to be used to predict the performance of coupled coils.

F2: FINAL COILS USED

The 'figure 8' coils were based on the test coils described above.

a) Impedance matching.

The optimum series load resistance calculated in section F1(c) is

$$R_L = 28.17 \text{ ohms.}$$

From Appendix C, equation (IV_C), the equivalent parallel resistance is:

$$R_b = R_a \left[1 + \frac{1}{\omega^2 C_a^2 R_a^2} \right]$$

where

$$R_a = R_L + R_S$$

Also at resonance, $\omega^2 = \frac{1}{L_S C_a}$

$$\therefore R_b = R_a \left[1 + \frac{\omega^2 L_S^2}{R_a^2} \right]$$

$$= (26.17 + 7.33) \left[1 + \frac{1.422 \times 10^{12} \times 16.1 \times 10^{-8}}{1260} \right]$$

$$= 35.5(1 + 181.9)$$

$$= 6.45 \text{ Kohms.}$$

Resistance of bladder $R = 100 \text{ ohms}$

Source plus diode resistance $r = 15 \text{ ohms}$

\therefore From Appendix E, equation (II_E),

$$\frac{R}{r} = \frac{100}{15} = 6.66 = \frac{\pi}{\tan \theta - \theta}$$

From the curve, $2\theta = 110^\circ$; $\theta = 55^\circ = 0.96 \text{ rads.}$

Combining equations (II_E) and (III_E),

$$\begin{aligned} R_{eq} &= \frac{\pi r}{\theta - \sin \theta \cos \theta} \\ &= \frac{\pi \times 15}{0.96 - .819 \times .573} = \frac{\pi \times 15}{0.96 - 0.4695} = \frac{\pi \times 15}{0.4905} \\ &= 96 \text{ ohms.} \end{aligned}$$

where $R_{eq} \equiv$ equivalent load the source 'sees' with smoothing capacitor in circuit.

From Appendix D, equation (II_D), where

$$R_1 \equiv R_b; R_2 \equiv R_{eq},$$

$$\left(\frac{N_1}{N_2} \right)^2 = \frac{6450}{96} \approx 67.2$$

$$\therefore \frac{N_1}{N_2} = 8.2$$

Since $N_1 = 260$ turns

$$N_2 = \frac{260}{8.2} = 31.7$$

≈ 32 turns

b) Primary 'figure 8' coil.

If identical primary and secondary windings are used, the reflected impedance into the primary coil is:

$$R_S' = \frac{w_M^2}{R_a}$$

$$= \frac{740}{35.5}$$

$= 20.8$ ohms.

Total primary resistance

$$R_{Pri} = R_P + R_S'$$

$$= 7.33 + 20.8$$

$= 28.13$ ohms.

Since the final circuit is parallel-tuned, equation (IV_C) yields the equivalent parallel resistance:

$$R_{b_P} = R_{Pri} \left[1 + \frac{w_{L_P}^2}{R_{Pri}^2} \right]$$

$$= 28.13 \left[1 + \frac{1.422 \times 10^{12} \times 16.1 \times 10^{-8}}{791} \right]$$

$$= 28.13(1 + 289)$$

$= 8.15$ Kohms.

If the resistance the amplifier 'sees' is chosen as 11 ohms, from Appendix D, equation (II_D),

$$\left(\frac{N_1}{N_2}\right)^2 = \frac{11}{8150} = 13.5 \times 10^{-4}$$

$$\frac{N_1}{N_2} = 0.03672$$

Since $N_2 = 260$ turns

$$N_1 = 260 \times 0.03672$$

$$= 9.54 \text{ turns}$$

$$\approx 10 \text{ turns.}$$

Using equation (I_D), if the supply voltage $E_1 = 10^V$ then

$$\begin{aligned} E_2 &= E_1 \cdot \frac{N_2}{N_1} \\ &= 260^V \end{aligned}$$

This voltage is sufficient to cause breakdown of the insulation. The primary coil was therefore modified. Instead of using 7 strands and 130 turns per coil-side, 70 strands and 13 turns per coil-side were used. The inductance and resistance of the coil are decreased by a factor of 100, whilst the mutual inductance is decreased by a factor of 10. The Q-factor, coupling coefficient and efficiency remain the same.

$$\text{Thus } L_p = 4.012 \text{ } \mu\text{H}$$

$$R_{DC} = 0.0246 \text{ ohms}$$

$$R_{RF} = 0.0733 \text{ ohms}$$

$$M = 2.28 \text{ } \mu\text{H}$$

$$f = 190 \text{ KHz.}$$

Series impedance of the primary coil

$$\begin{aligned}
 R_{Pri} &= R_p + \frac{w_m^2}{R_a} \\
 &= .0733 + \frac{1.422 \times 5.2}{35.5} \\
 &= .0733 + .2082 \\
 &= 0.2815 \text{ ohms.}
 \end{aligned}$$

Equivalent parallel resistance

$$\begin{aligned}
 R_{bp} &= .2815 \left[1 + \frac{1.422 \times 16.1}{.0732} \right] \\
 &= .2815(1 + 289) \\
 &= 81.4 \text{ ohms.}
 \end{aligned}$$

The amplifier load was chosen as 11 ohms for the type of transistor used
(Type 80124; $V_{CE_{MAX}} = 45^V$; $I_{C_{MAX}} = 4^A$)

$$\therefore \left(\frac{N_1}{N_2} \right)^2 = \frac{11}{81.4} = 0.1352$$

$$\frac{N_1}{N_2} = 0.368$$

$$N_2 = 26 \text{ turns}$$

$$\therefore N_1 = 26 \times 0.368 = 9.55$$

$$\approx 10 \text{ turns}$$

$$\text{If } E_1 = 10^V$$

$$E_2 = 10 \times \frac{26}{10} = 26^V$$

which is well below the value of voltage needed to cause insulation breakdown.

The following is a table comparing theoretical and measured parameters for all three coils at a spacing of 12mm.

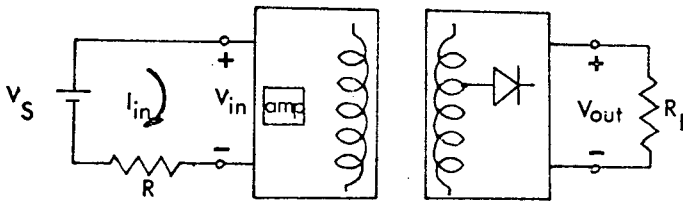
MEASURED								
COIL PAIR	TOTAL TURNS	TAPPING	L	R_{DC} (ohms)	R_{RF} (ohms)	f (KHz)	M (μH)	% \mathcal{Q}_{AC-AC}
1 PRIMARY			5.2 μH	0.079		190		46
SECONDARY			.41 mH	2.67	7.5		3.33	
2 PRIMARY			5.2 μH	0.083		160		51.3
SECONDARY			.408 mH	2.63	5.5		3.2	
3 PRIMARY			15.2 μH	0.107		130		87.1
SECONDARY			1.363 mH	4.45	7.4		38	
CALCULATED								
1 PRIMARY	26	10	4.012 μH	0.0246	0.0733	190		58.5
SECONDARY	260	32	.4012 mH	2.46	7.33		2.28	
2 PRIMARY	26	10	4.012 μH	0.0246	0.051	160		64.4
SECONDARY	260	33	.4012 mH	2.46	5.1		2.28	
3 PRIMARY	13	7	15.07 μH	0.0468	0.0781	130		95.4
SECONDARY	130	21	1.507 mH	4.68	7.81		41.3	

The experimental method used is not accurate enough to obtain a meaningful result when measuring the RF resistances of the primary coils since the source resistance R (see Appendix F1(e)) cannot be made small compared to the resistance of the primary coils.

As can be seen from the table, the discrepancy between calculated and measured values is large. It must be remembered that each primary winding consists of 70 strands. It is therefore impossible to wind this coil exactly into the available space resulting in a larger coil and a greater length of wire being used than that calculated for.

The following measurements were taken on coil-set 1 in order to evaluate the efficiency of the amplifier:

$\% \eta_{\text{DC-DC}}$



$$V_{\text{IN}} = 8^{\text{V}}$$

$$I_{\text{IN}} = 0.95^{\text{A}}$$

$$P_{\text{IN}} = 7.6^{\text{W}}$$

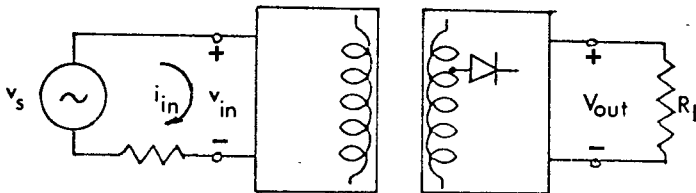
$$V_{\text{O}} = 10.6^{\text{V}}$$

$$I_{\text{O}} = 0.108^{\text{A}}$$

$$P_{\text{O}} = 1.168^{\text{W}}$$

$$\% \eta_{\text{DC-DC}} = 15.36\%$$

$\% \eta_{\text{AC-DC}}$



$$\% \eta_{AC-DC} = 31.5\%$$

∴ Efficiency of amplifier

$$\% \eta_{AMP} = 48.6\%$$

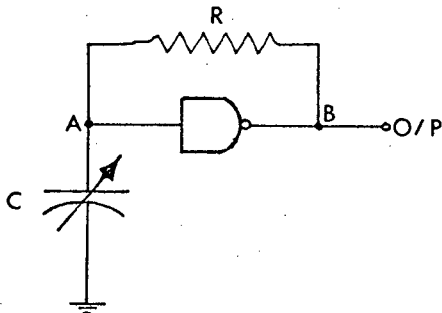
CHANNEL	$\% \eta_{DC-DC}$
1	15.36
2	17.15
3	32.55

APPENDIX G: THE LOGIC CIRCUITRY

G1: ASTABLE MULTIVIBRATOR (AMV)

Logically, each circuit in the SN7413N⁷⁸ functions as a four-input NAND gate.

Consider the following circuit:



If at time $t = 0$, say, point A is at logical '0', then point B will be at 'logical '1'. The capacitor will then charge up via resistor R with a time constant RC . Then point A will be at logical '1' and thus point B will be at logical '0'. The capacitor will now discharge, again with a time constant RC until point A is again at logical '0'. The process thus repeats itself continuously.

G2: DUAL JK FLIP FLOPS

The characteristic equation of the JK flip flop, where n = time of

input, is:

$$Q^{n+1} = (\bar{K}Q + J\bar{Q})^n$$

For every three clock pulses supplied by the AMV, the dual JK flip flops must produce the following sequence:

t^n		t^{n+1}	
Q_1	Q_2	Q_1	Q_2
0	0	1	0
1	0	1	1
1	1	0	0

where

'1' \equiv high output

'0' \equiv low output

Thus $Q_1^{n+1} = (\bar{Q}_1\bar{Q}_2 + Q_1\bar{Q}_2)^n$

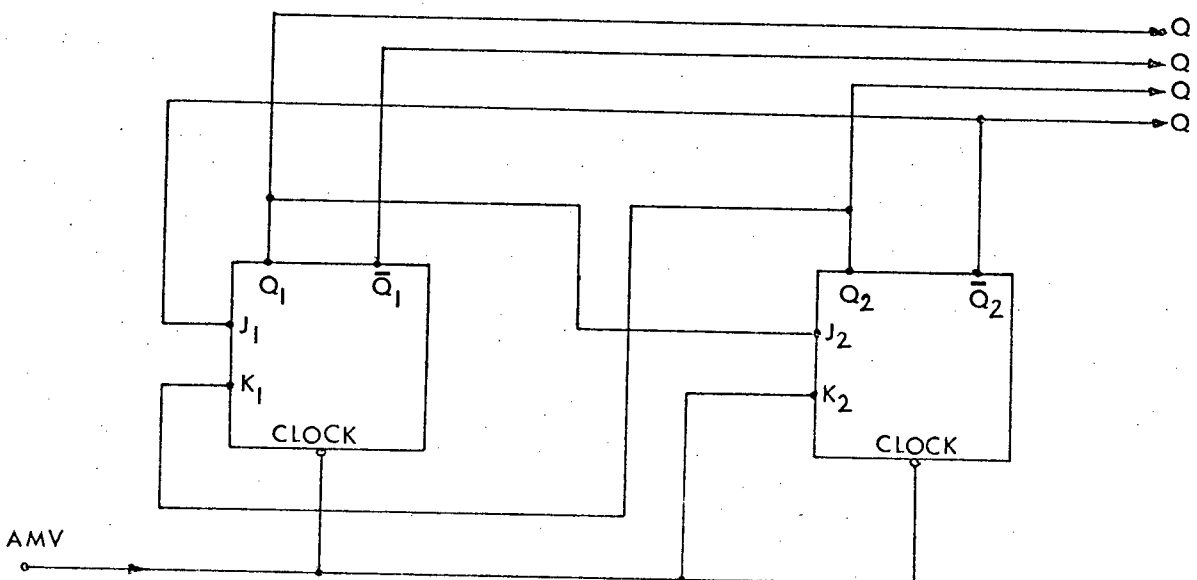
$$Q_2^{n+1} = (Q_1\bar{Q}_2)^n$$

Thus $J_1 = \bar{Q}_2$ $K_1 = Q_2$

$$J_2 = Q_1$$

$$K_2 = 1$$

The two flip flops are therefore connected in the following manner:



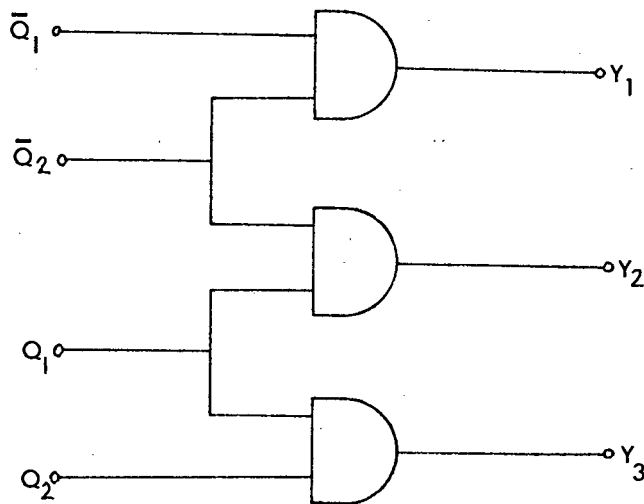
Thus the output from the flip flops is:

Q_1	\bar{Q}_1	Q_2	\bar{Q}_2
0	1	0	1
1	0	0	1
1	0	1	0

It can be seen that a logical '1' appears at two of the outputs at each bit time.

G3: AND Gates

In order to obtain one pulse only at each instant in time, each pair of outputs from the JK flip flops which have a logical '1' at the same bit time are fed into the two inputs of an AND gate as shown below:



The output of the AND gates is:

y_1	y_2	y_3
1	0	0
0	1	0
0	0	1

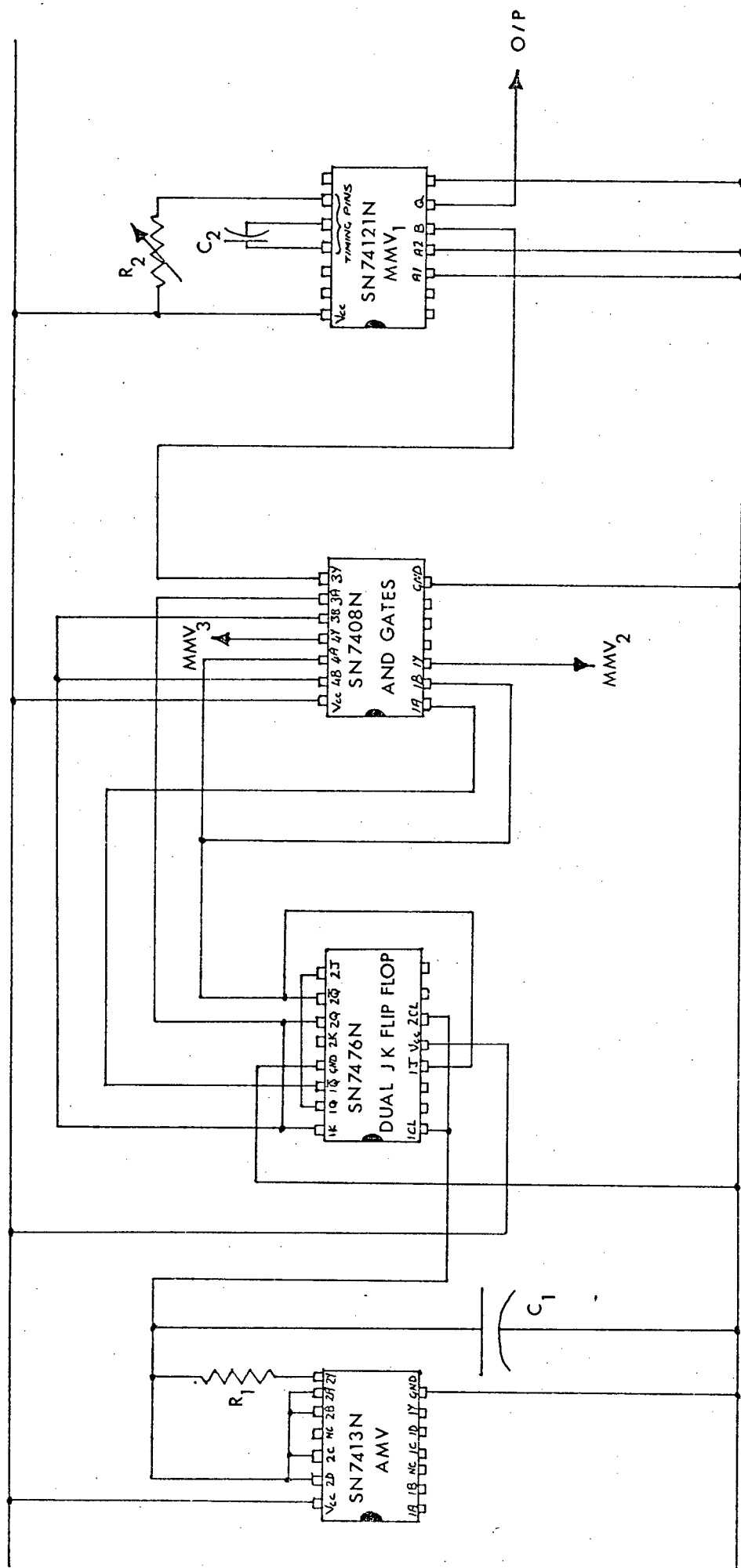


Fig. 15 LOGIC CIRCUITRY AND CONNECTIONS

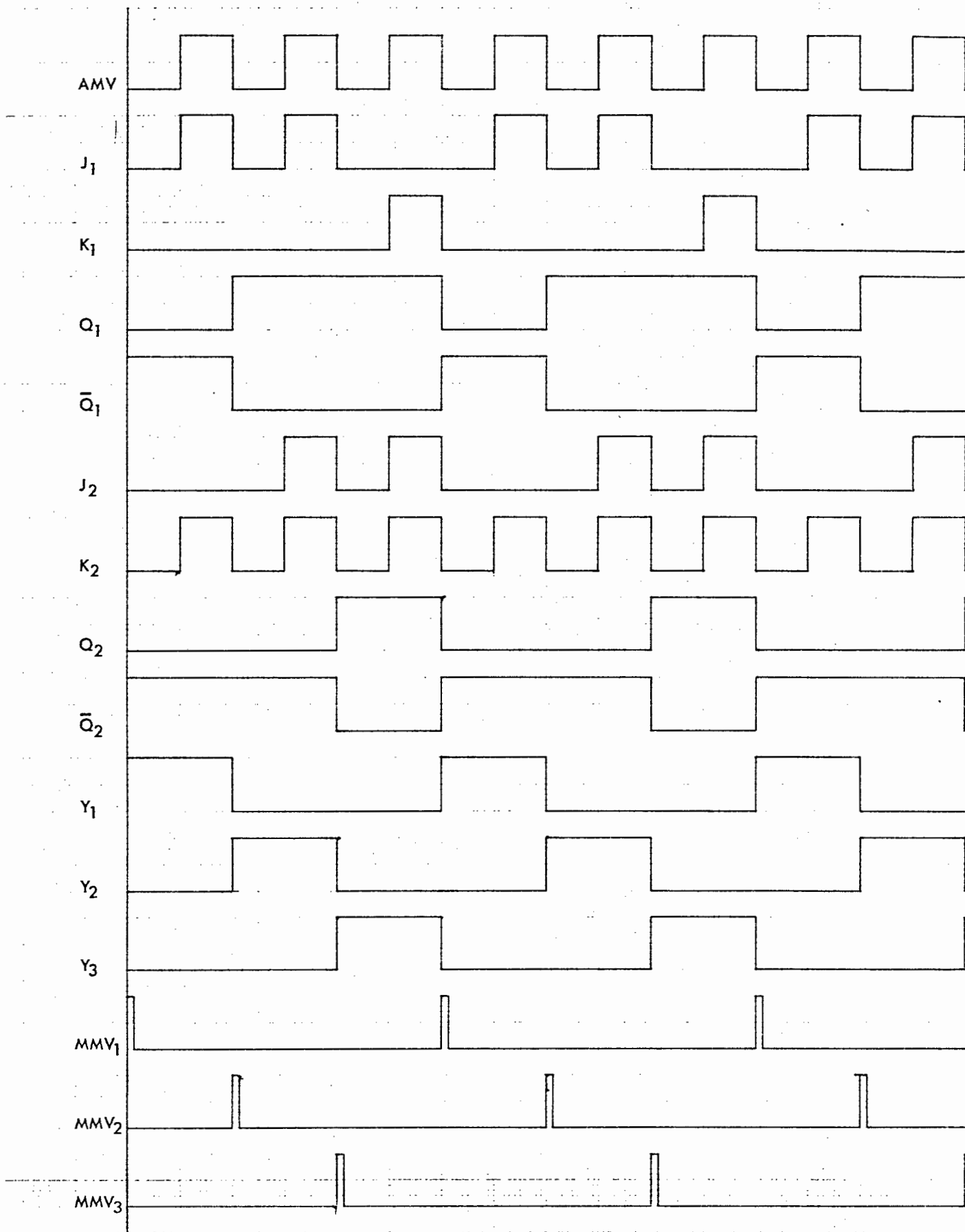


Fig. 16 OUTPUT WAVEFORMS OF LOGIC CIRCUITRY

Since the frequency of the AMV is 60 Hz, the frequency of pulses appearing at the output of any one AND gate is 20 Hz which is the required frequency.

G4: MONOSTABLE MULTIVIBRATORS (MMV's)

The purpose of the MMV's is to adjust the width of each modulating pulse to the required duration. This is achieved by means of a timing resistor and capacitor. Using a $0.1 \mu\text{F}$ capacitor with a variable 10 Kohms resistor enables the pulse width to be varied from about 100 μs to 1 ms.

APPENDIX H: LIST OF COMPONENTS

The following is a list of components used. The numbers correspond to those given in the circuit diagrams of Figures 5 and 15. Subscripts 1, 2 and 3 refer to each of the three channels.

<u>RESISTORS</u>	<u>COMPONENT NUMBER</u>	<u>VALUE</u>	<u>TYPE</u>
All values in ohms	R_1	330	Carbon resistors rated at $\frac{1}{4}$ watts unless otherwise specified. TRIMMING POTENTIOMETER
	R_2	10 K	
	R_3	1 K	
	R_{4_1}	4.7 K	TRIMMING POTENTIOMETER
	R_{4_2}	4.7 K	TRIMMING POTENTIOMETER
	R_{4_3}	10 K	TRIMMING POTENTIOMETER
	R_{5_1}	18 K	
	R_{5_2}	22 K	
	R_{5_3}	47 K	
	R_6	18 K	
	R_7	50	(100//100 ohms)

RESISTORSCOMPONENT NUMBERVALUETYPE R_8

1 K

 R_9

10 K

TRIMMING POTENTIOMETER

 R_D

1 K

CAPACITORS

All values in
microfarads
unless other-
wise specified

 C_1

22 + 8

16^V

TANTALUM

 C_2

0.1

MYLAR

 C_3

1000

16^V

TANTALUM

 C_{4_1}

220 pF

CERAMIC

 C_{4_2}

220 pF

CERAMIC

 C_{4_3}

120 pF

CERAMIC

 C_5

0.1

MYLAR

 C_6

0.47

SILVER MICA

 C_{P_1}

0.033

POLYESTER

0.033

POLYESTER

0.01

POLYESTER

0.1

POLYESTER

 C_{P_2}

0.01

POLYESTER

0.022

POLYESTER

0.047

POLYESTER

0.15

POLYESTER

 C_{P_3}

0.033

POLYESTER

0.1

POLYESTER

<u>CAPACITORS</u>	<u>COMPONENT NUMBER</u>	<u>VALUE</u>	<u>TYPE</u>
	C_{S_1}	2200 pF	POLYESTER
	C_{S_2}	2700 pF	POLYESTER
	C_{S_3}	1500 pF	SILVER MICA
	C_{S_m}	0.6	6.3 ^V TANTALUM
	C_D	10	16 ^V TANTALUM
<u>TRANSISTORS</u>			
All transistors are silicon NPN types	Q_1	BC109	Manufactured by S.T.C.(S.A.)
	Q_2	BC109	
	Q_3	BC109	
	Q_4	BC109	
	Q_5	BC109	
	Q_6	BD124	Manufactured by Motorola Semiconductor Products Inc., (USA)
<u>DIODES</u>			
Silicon	D_1	0A5	Philips (Netherlands)
	D_2	1N4936	Motorola Inc., (USA)
<u>SWITCH</u>			
	S_1	Button	Normally open
<u>BATTERIES</u>			
	8 x 1.2 ^V	SANYO	N-450AA

<u>LOGIC CIRCUITRY</u>	<u>COMPONENT NUMBER</u>	<u>TYPE</u>	
	SN7413N	AMV	Manufactured by Texas
	SN7476N	DUAL JK FLIP FLOP	Instruments Inc., Dallas, Texas, USA.
	SN7408N	AND GATES	
	SN74121N	MMV	

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